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SOCIAL ASPECTS OF THE MEDICAL USE OF PSYCHOTROPIC DRUGS

Edited by: RUTH COOPERSTOCK

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Edited by RUTH COOPERSTOCK



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The discussions that took place during this Symposium will be published separately as a supplement to this volume.

International Drug Control and the Pharmaceutical Industry

Kettil Bruun¹

AN INTRODUCTORY NOTE

My intention in this paper² is to point out gaps in our knowledge (rather than to present new data) that will help to formulate the structure of the problems involved. The difficulties are obvious. Industrial data are to a great extent unavailable and secret, and the activities of a pressure group such as industry cannot be described without large-scale empirical research. The situation is not unique: insiders possess knowledge but are prepared to divulge only a selected number of facts, and are moreover tied to economic interests. Outsiders might be able to describe the general position of industry in today's world, but they experience difficulties in enlarging upon such general statements. The problem at hand thus relates to how one can structure a research program that aims at a balanced synthesis of the role of industry, with due regard to the positive effects of dependence-producing drugs, as well as the negative ones. How should such a research program be structured so that it may provide guidelines not only for the general control of drugs but also for a specific control policy directed towards the pharmaceutical industry?

Mention is due of a number of limitations in my paper. First, drugs here denote dependence-producing drugs. Secondly, the more general aspect of drug safety control will be ignored. Thirdly, the perspective of industry is restricted in scope, and primarily concerns its role as a pressure group. Furthermore, national examples will be omitted in favour of an international perspective.

¹Finnish Foundation for Alcohol Studies Pitkäsillanranta 3B, 00530 Helsinki 53 Finland.

²Some parts of this paper have been extracted from a forthcoming book (Bruun, Pan, and Rexed: The Gentlemen's Club. International control of drugs and alcohol, manus 1973).

Finally, reference is necessary to a basic approach that influences the line of thought in this paper. In the discussions on international control, a great deal of confusion seems to arise in speaking of supply and demand. Sometimes these are treated as unrelated concepts and alternatives in control policies: recently, a lot more emphasis seems to have been laid upon the demand side. I would submit that those concepts are closely linked to each other, and that the most important aspect of drug control is the nature of the relationship that is unfortunately recognized primarily only in discussions on illicit trade. The fundamental point, too often neglected, is that legal suppliers create demands. The mechanisms whereby demands are created by those with economic interests, principally by the pharmaceutical industry, are of crucial importance.

AN HISTORICAL PERSPECTIVE

In the days of the League of Nations, the Advisory Committee on Traffic in Opium and Other Dangerous Drugs was the key body responsible for international control. This body, primarily representing governments with industrial interests, had a composition that obviated the need for private pharmaceutical pressure group activity. Unlike attempts to influence decisions in domestic politics, influence at the international level could occur without any activity being displayed by the interest group concerned on the international stage. At the Hague Conference in 1912, the country most responsible for the dilution of a resolution on manufactured drugs was Germany, a major manufacturer of opium derivatives, and possessing almost a monopoly of cocaine production. Its chemical industry had exerted a great deal of pressure on the German Government not to attend the conference: thus the German delegation "was out to scuttle any strong measures that might jeopardize the favoured position of their manufacturers" (1, p 102).

Although it is only in relatively recent times that commercial interests in pharmaceuticals have become visibly active at an international level in the area of drug control, lobbying efforts by physicians and pharmacists at the domestic level have had a long history (2).

However, international pharmaceutical associations have existed since the twenties. For example, at the 1924 Geneva Opium Conference, the International Pharmaceutical Federation was sufficiently interested to write to the President of the conference with the request that favourable note be taken of the recommendations which the Federation had arrived at during its meeting in Paris. Some of these recommendations read as follows:

...it will be necessary that the law regulating the traffic in narcotics in the different countries shall not impose upon pharmacists administrative provisions which might prove a source of worry and annoyance and hinder them in the conduct of their business.

...the prohibition to supply these medicaments to customers without a medical prescription should not, however, prevent the sale of medicaments containing so small a quantity that there can be no question of abuse. It is not necessary to demand more than is laid down in Article 14(b) and (c) of the Opium Convention.

...Provisions regulating the sale of narcotics in pharmacies, and any registers and lists that may be prescribed, should be as simple as possible and drawn up in agreement with the pharmaceutical profession before being enforced. (3, p 332)

One important motive for holding the 1924 Geneva conference and a later one in 1931, was concern over the extensive amount of illicit trafficking, a business involving many supposedly law-abiding European pharmaceutical firms. The Advisory Committee saw it as a question of overproduction and the diversion of "surplus" drugs into illegal channels. As the Chinese member of the Advisory Committee pointed out, Germany, Great Britain, Japan, Switzerland and the United States were all turning out "morphine by the ton, which was purchased by the smugglers by the ton." It was as if, he observed, the manufacturing countries were "competing with each other owing to the fact that the business was a very profitable one, although the profits went only to smugglers and a few manufacturers. . . He could not understand why civilized countries should allow such a scandalous state of affairs to continue unchecked. . ." (4, p 73). The large influx of European morphine and heroin into China during the 1920s had been in response to the elimination of the Indian opium trade, and the suppression campaign within the country. Small quantities of both drugs were imported for medical use from Europe (for a time they were believed to be a cure for opium addiction) but the distinction between "medical" and "non-medical", as that between legal and illegal, became progressively blurred and a great deal of smuggling occurred (5).

Attempts to control diversion from drug manufacturers were often thwarted by the fact that these manufacturers knowingly supplied drugs to smugglers (6). Switzerland, for instance, was a particularly safe place from this point of view, not only for irresponsible drug firms but also for money transactions associated with drug deals. What came to be known as the "Canton Road Smuggling Case", which was handled by the Mixed Court of Shanghai in 1925, offers an illustration of this. The case involved 180 chests of opium shipped from Constantinople and sold in China, and 26 boxes containing mostly heroin imported from Basle, Switzerland by a Chinese dealer, Gwanho. Documents produced at the trial revealed that a considerable trade had been plying between Gwanho and the Swiss drug firms Hoffman La Roche and MacDonald and Co. The latter company had been "notoriously engaged in the illicit traffic", and had operated for a time from Germany, where it transacted a considerable trade in drugs and arms to the Far East. But German inquiries into the dealings of this company had driven it to seek a "more convenient centre", which it subsequently found in Switzerland. A Stuttgart firm was involved too, and a telegram was found showing that Gwanho had remitted £2,000 sterling to it through the Schweizerische Kreditanstalt of Zürich (7). But pressure applied to Switzerland by other members of the Advisory Committee was steadily resisted. When another case of illicit traffic involving Hoffman La Roche was discussed, protests were voiced by the British delegate that this threw "a lurid light on the character of the firm". These were supported by the Chairman, Sir John Campbell, who personally "had no doubt whatever that Hoffman La Roche and Company was not a firm to which a licence to deal with drugs should be given". The Swiss representative however persisted in his attitude that the Swiss Government was not responsible and could not justifiably intervene (6, pp 67-69).

The records of the Opium Advisory Committee abound with cases of illicit transactions implicating European pharmaceutical firms. One of the most widely publicised cases involved Naarden, a Dutch firm, which between 1927 and 1928 had amassed about 850 kilograms of morphine, 3,000 kilograms of heroin and 90 kilograms of cocaine, most of which was smuggled into China. The supplies came mainly from three firms in Germany, Switzerland and France (8).

Gradually, however, international pressure succeeded in persuading drug manufacturing countries to apply adequate controls over their drug industries so that overproduction was by and large brought under control. However, the implementation of the 1925 and 1931 Conventions controlling international trade and limiting production had a double-edged effect: while authorized manufacture was regulated, underground factories started to appear. Nonetheless, I would argue that in this instance we have one of the few examples in which the beneficial effects of control outweigh the harmful ones.

Yet the problem of overmedication was by no means solved. The 1931 Convention introduced a system, whereby governments were supposed to estimate the medical need for their countries of those narcotics under international control. Already before the Convention was accepted, the Health Committee of the League of Nations was approached to establish the world medical requirement of opium. First a rate of 600 milligrams of raw opium for each citizen for one year was recommended. Subsequently, the Committee adopted a norm of 450 milligrams, consumption above which level was to be considered not only unnecessary but also harmful, and consumption below which was to be an indication that part of the population was being deprived (9). Such a norm corresponds to the world's legitimate requirement of 720 tons. Interestingly enough, the U.S. Congress had in a resolution of 1923 declared that 100 tons would satisfy the need (10).

THE PRESENT SITUATION

To appreciate the differences between today and the twenties, we should remember that (a) the pharmaceutical industry is a creation mainly of the period after World War II, and its rate of expansion is high in comparison with most other branches of industry; (b) the pharmaceutical industry is in a deviant position in comparison with most other industries, as it is more research-based, and a large part of the sale is channelled through two professions, doctors of medicine and pharmacists; (c) the general development of economic integration has, independently of drug control, created problems for national drug industries and a need for cooperation between pharmaceutical industries on an international level, and (d) the national legislation on drugs, strongly influenced by the thalidomide case, has created special problems for international trade in pharmaceuticals. This legislation, together with various health insurance schemes, has had an influence on the relation between industry and governments.

We can see the necessity for a discussion on drug control and industry needs with due recognition always of general trends in society.

With regard to the industry's activities as a pressure group, the most important notion is that concerned with changes in the degree of cooperation.

Common interests among pharmaceutical manufacturers have led them to form such joint organizations as the "Groupement International de l'Industrie Pharmaceutique des Pays de la Communauté Economique Européenne" (GIIP), established in 1959, and the "Pharmaceutical Industries' Association in the European Free Trade Area" (PIA). In 1968, these groups, together with their counterparts in the United States and Canada, formed the "International Federation of Pharmaceutical Manufacturers Associations" (IFPMA). IFPMA was admitted as a non-governmental organization (NGO) to the World Health Organization (WHO) in January 1971. In comparison with the International Council of Alcohol and Addictions (ICAA), which struggled for 20 years to achieve such a position and was turned down because it did not meet scientific requirements, the

procedure seems swift indeed. In fact, the WHO Standing Committee on non-governmental organizations suggested in January 1971 that WHO should follow the development of the organization and postpone a decision. The Board did not follow this advice, however, and accepted the application without delay. At the Board meeting, the International Pharmaceutical Federation, another NGO, was represented by a vice-director of the Swiss drug firm Ciba-Geigy, who one year later appeared as an IFPMA representative (11, p 273) in the WHO Executive Board's listing of NGOs. The acceptance of IFPMA as an NGO to WHO has led to its being accepted in a similar position by the U.N. Economic and Social Council (ECOSOC).

Although ECOSOC has been careful in granting status to profit-making businesses, organizations seeking such status can and do register under non-profit-making codes, and gain admittance. While not profit-making in the strict sense, such organizations may still pursue the furtherance of their members' commercial interests. On the other hand, a commercial body may be considered of such great use to an organization that the profit factor is ignored.

Pickard offers an example of this:

The World Health Organization, for example, because of a possible need for close cooperation with great pharmaceutical businesses, was careful not to include the non-profit making proviso among its criteria for the granting of official relations to an NGO (12, p 43).

Inclusion of the representatives of private organizations in conference delegations is another familiar practice. A joint report by UNESCO and the International Institute of Administrative Sciences (1951) notes that some governments,

notably the US, prefer to give certain non-official groups the opportunity to express themselves as delegation members. At the San Francisco Conference which created the UN Charter in 1945, representatives of numerous private organizations were invited to act as "consultants" to the American delegation. For financial reasons this practice was scarcely feasible for overseas governments.

Another example is afforded by the U.S. delegation to the International Health Conference which created WHO in 1946. The representatives of the American Medical Association (AMA) formed an integral part of the delegation. The AMA was opposed to any action by WHO which might promote "socialized" medicine, and thought that the organization should not concern itself with "the care of the sick and the social organization related to the practice of medicine." (13, p 178) Yet another example is the inclusion in the Swiss delegation to the Vienna Conference in 1971 of employees of the two large pharmaceutical companies of Switzerland: Hoffman La Roche and Ciba-Geigy.

A well-known feature of the relation between large-scale private enterprise and national government is the interchange of high-level personnel between the two concerned. Senior civil servants often take up positions on the boards of private companies when they reach retiring age, and the phenomenon of clientalism is well known particularly in the United States (14). In the drug field, one can cite several examples of international civil servants leaving the service to join the pharmaceutical industry. The late Gilbert Yates, a former Director of the UN Division of Narcotic Drugs, became the Director of the Association of British Pharmaceutical Industry; Adolf Lande, previously Secretary of the INCB, was afterwards with the American Pharmaceutical Manufacturers'

Association; and Hans Halbach, a former Chief of the WHO Drug Dependence Unit and Director of the Division of Pharmacology and Toxicology, is now employed by the Swiss drug company Hoffman La Roche.

To what extent the pharmaceutical industry has been able to exercise influence in the area of drug control is, of course, an open question. That its interests were a decisive factor throughout the development of the international drug control system is manifest in all the more systematic historical accounts of narcotics control (1, 2, 15). More recent interest is attached to the influence on the development leading to the Vienna Convention. Quite clearly, one motive behind the creation of IFPMA was that of activities intended to ward off international control. At an early stage — at least implicitly — IFPMA adopted a negative attitude towards the creation of a new protocol, but at a later meeting IFPMA produced an alternative text to the draft protocol, with some points being accepted in the final version. In recent bulletins of IFPMA, a great deal of emphasis is laid upon cooperation with WHO and various UN organs. For instance, the importance of having IFPMA represented not only on the WHO Assembly and WHO Board meetings, but also on regional meetings is stressed. Emphasis is laid upon loyalty to WHO, and the adherence to programs on drug safety. However, no attitude is adopted towards the Vienna protocol and the very non-existence of recommendations apparently implies that forces within industry are working against ratifications of the Vienna protocol.

What then are the consequences of the recently created relation between IFPMA and WHO? In discussing this we should pay due regard to the attitudes adopted by the WHO Drug Dependence Expert Committee. The standpoints of this body with respect to control express WHO policy. The attitudes taken towards the control of substances of morphine-type have been fairly rigorous, and a possibly favourable effect of this control is that some innovations by the pharmaceutical industry in the fifties were never marketed. As far as other dependence-producing drugs are concerned, however, the situation is different. Agents of international control had always to consider political realities, not only properties of pharmaceutical products. When Pablo Wolff was head of the relevant office in WHO, there was a consistent endeavour to control barbiturates, amphetamines, and so on also, but by reason of the attitude of the United States towards the control of barbiturates, international control in this area was never suggested (16). His successor at WHO, Hans Halbach, made no attempt to introduce such control. Psychotropics control was considered a matter of national policy but WHO has never developed the principles of control policy. As far as I can see, the acceptance of the Vienna protocol is primarily due to forces external to industry and WHO, and probably very little tension existed between the two. However, one can see that more direct co-operation between industry and WHO might have led to a more forceful resistance to the Vienna protocol. My point is that the creation of IFPMA, and its position, will prove a serious obstacle to any future proposal of control that is not accepted by industry and WHO. At the same time, the industry, by virtue of its new position, has to play the role of the one responsible, and some cleaning up of the most obvious uncontrolled activities is to be expected. WHO will gain in the research area from cooperation with IFPMA, and will particularly favour research-based industry rather than the imitators. Nevertheless, it can not be expected that the more fundamental question of the role of industry in the creation of demands will be raised by WHO.

If my interpretation is correct, we have very little to expect from WHO in terms of innovations in control policy, or in terms of developing the fundamentals of control policy. Consequently, the research institutes working in the area of control policy must

give more consideration to this aspect. I wish to propose the following measures in the area of research.

1. It is necessary to develop international statistics on production, trade, and the consumption of psychotropics. This will partly be handled by the International Narcotics Control Board (INCB) according to the Vienna Convention; however, it is imperative that not only those substances under control should be included, but also those which may function as substitutes. Every attempt to achieve a rational control policy must be based upon these fundamental data, and a definite need exists for the use of such statistics to facilitate studies of the effects of various measures of control policy (17).

2. The development of the drug industry in developing countries must be considered in the light of special problems posed by dependence-producing drugs. The programs formulated by United Nations Industrial Development Organization (UNIDO), and supported by IFPMA and WHO, might lead to the introduction of overmedication in these societies. Evaluation and analysis of these programs are of extreme importance.

3. In forecasts of the consumption of pharmaceuticals, psychotropics are considered as an expansive sector. It is obvious that notwithstanding the non-acceptance of public advertisement, there are several ways of marketing (18). It is imperative to study how marketing is in fact effected.

4. The relationship between the medical profession and the industry should be the object of a thorough study.

5. The so-called "research-based pharmaceutical industry" poses special problems and should be studied in the light of general research policy. What are the actual research programs? Is research orientated to increase consumption rather than to improve health?

6. To ensure a more complete understanding of industry, there should be case studies of large pharmaceutical firms.

7. To acquire an historical perspective, a study should be made of the relationship between the pharmaceutical industry and international control bodies during the period between the World Wars. Access to the archives of the Permanent Central Opium Board should accordingly be granted.

CONCLUSION

Let me conclude by summarizing a few essential points.

The importance of the pharmaceutical industry in creating new demands of psychotropics is obvious. Consequently, industry is a legitimate and crucial research object, although so far neglected.

Focal points in an outlined research program are stressed.

The need of perceiving industry as a research object is strengthened by the fact that industry also is a strategic position as an object for control policy.

A successful control policy is oriented to those producing and supplying drugs rather than to individual consumers. An historical example of successful control of industry is given.

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Regulatory Control of the Canadian Government over the Manufacturing, Distribution and Prescribing of Psychotropic Drugs

Alexander B. Morrison¹

Traditionally, Canadian policy with respect to the non-medical use of psychotropic drugs has depended heavily upon law enforcement. Social response to drug abuse obviously includes many other ways of dealing with real or apprehended problems. These include education, and the provision of information; research; medical treatment; social influences from the family, church and social groups; peers; and development of personal responsibility and self restraint. The law is only one way of dealing with drug problems. Historically, however, it has had the predominant influence on Canadian policy in this field, perhaps, in part, because it has seemed to many to provide simple, clear-cut answers to problems of baffling complexity, and to satisfy puritanical views about the drug user as a moral degenerate in need of punishment.

In Canada, legal control over drugs with a potential for abuse began in the early 1900s. Legislation to prohibit the importation, manufacture and sale of opium for other than medicinal purposes was enacted in 1908, following a report by William Lyon MacKenzie King (then Deputy Minister of Labor) entitled "The Need for Suppression of the Opium Traffic in Canada". The legislation, which made unauthorized possession of opium an offence, was intended to control trafficking in the drug, which had become prevalent among the Chinese on the West Coast. *The Opium and Drug Act* of 1911 regulated the importation, manufacture, sale and possession of cocaine, opium, morphine and eucaine.

It soon became evident that additional legislation was required to deal more effectively with the increasing problem of trafficking in narcotic drugs. Accordingly, an Act

¹ Assistant Deputy Minister, Health Protection Branch, Health and Welfare Canada, Tunney's Pasture, Ottawa K1A 0L2, Canada.

entitled *The Opium and Narcotic Drug Act* was passed by Parliament in 1920. This Act, which amended *The Opium and Drug Act* of 1911, provided for more complete control of drugs on the domestic market as well as in the international trade. The administration of this Act was assigned to the Department of Health.

Gradually, over the years, other drugs were added to the list of those controlled, and the severity of penalties associated with offences was increased. These actions, of course, reflected the concern of legislators and the public about the effects of drug users on society. Unfortunately, they often were based more on misinformation and fear than on facts. LeDain *et al.* (1) have suggested, in fact, that in the early years, Canadian drug laws to a very large extent reflected popular attitudes and policy towards persons of Asiatic origin, rather than scientific knowledge about the harm associated with drug use.

In 1923, cannabis was added to the list of drugs controlled by *The Opium and Narcotic Drug Act*. At that time, there was essentially no use of the drug by Canadians, and therefore no social concern about it. Although the reasons for its inclusion in the Act are somewhat obscure, it appears that Col. C. Sharman, then Director of the Federal Division of Narcotic Control, returned from meetings of the League of Nations convinced that cannabis soon would fall under international control. In anticipation of such action, he moved to have it added to the list of drugs controlled under Canadian law. International control over cannabis actually began in 1925. LeDain *et al.* (2) have suggested that the book entitled *The Black Candle*, which gave lurid descriptions about the supposed menace of cannabis, and its purported ability to produce insanity and moral degeneracy, had some influence on the initial Canadian decision to control the drug. There is, however, no real evidence to support this view.

The Opium and Narcotic Drug Act was replaced in 1961 by the *Narcotic Control Act*. This Act reflected, in part, concerns about trafficking in drugs expressed in 1955 by a Special Committee of the Senate of Canada. This Committee recommended heavy compulsory minimum sentences for trafficking in drugs, and "a penalty of the utmost severity" for importation of drugs. The Committee rejected the idea that differences exist between addict and non-addict traffickers, and that motives for trafficking should appropriately be taken into account in setting penalties. The *Narcotic Control Act* partially satisfied the concerns of the Senate Committee by increasing the severity of penalties for trafficking in drugs, and imposing a minimum penalty (7 years in prison) for importation. Provision was made for compulsory detention and treatment of drug abusers, but this part of the Act has not been put into force by proclamation.

Canada has had a long record of cooperation in international attempts to control drugs. She took a leading part in establishment of the Single Convention on Narcotic Drugs, 1961, and was the first country to become a party to the Convention. Article 4 of the Convention requires that signatory countries must agree to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs listed in the Schedules to the Convention. Among drugs so controlled are some psychotropic drugs used in medicine, heroin and cannabis. Additions or deletions to the Schedules are made by the Commission on Narcotic Drugs of the U.N. Economic and Social Council. The Convention also requires (Article 36) that acts contrary to the provisions of the Convention be "punishable offences when committed intentionally", and that "serious offences shall be liable to adequate punishment particularly by imprisonment or other penalties of deprivation of liberty".

Psychotropic drugs not now controlled internationally under the Single Convention would be controlled by a proposed U.N. Convention on Psychotropic Drugs. Although

Canada collaborated fully in the development of the Convention on Psychotropic Drugs, our Parliament has not yet proclaimed it.

At the present time, the legal controls over the manufacturing, distribution and prescribing of psychotropic drugs in this country are provided by the *Narcotic Control Act* and by Parts III and IV of the *Food and Drugs Act*. The *Narcotic Control Act* regulates drugs that are classified as narcotics on pharmacological grounds, or are considered to require the same level of legal controls over their use as do the narcotics. Most of the drugs involved come under international control through the provisions of the Single Convention. Included are the opiates (*i.e.* drugs that come from the opium poppy such as morphine, heroin and codeine); synthetic analgesics such as pethidine (Demerol), methadone; cocaine; and *cannabis sativa*. The Schedule to the *Narcotic Control Act* also contains the drug phencyclidine, added in June of 1973.

Broadly speaking, Part III of the *Food and Drugs Act* governs certain depressants and stimulants. The depressants include the barbiturates and the non-barbiturate sedative methaqualone. The stimulants covered are the amphetamines and two drugs that are chemically related, phenmetrazine and phendimetrazine. The synthetic analgesic pentazocine (sold in Canada under the trade-name Talwin), also is included in Part III of the Act. Drugs covered in this Legislation are listed in Schedule G and are called Controlled Drugs. From the standpoint of Canadian legislation, this is the only group of drugs to which the term "Controlled Drugs" can be applied. Because of additional restrictions, the amphetamines, phenmetrazine and phendimetrazine are termed "Designated Drugs".

The third Statute covering psychotropic drugs is Part IV of the *Food and Drugs Act*, dealing with a group of 16 hallucinogenic chemicals, which have been subject to widespread abuse within recent years. The drugs involved include lysergic acid diethylamide (LSD), methylendioxyamphetamine (MDA), paramethoxyamphetamine (PMA) and harmaline. Drugs controlled under Part IV of the *Food and Drugs Act* are termed Restricted Drugs and are listed in Schedule H to the *Food and Drugs Act*.

From the standpoint of manufacturing, distributing and prescribing, Narcotic and Controlled Drugs can be taken together. The Legislation governing the legal distribution of these drugs is, with some very minor exceptions, similar.

There are five categories of outlets or individuals which handle Narcotic Drugs and Controlled Drugs in connection with their legitimate commercial business or professional duties. These are: (a) manufacturers and distributors; (b) pharmacists; (c) practitioners; (d) hospitals; and (e) researchers.

MANUFACTURERS AND DISTRIBUTORS

These include pharmaceutical firms which prepare and market products with a Narcotic or Controlled Drug content under their own company label, as well as firms classified as wholesalers or jobbers who distribute medication in the form in which it is received. Manufacturers and distributors who handle Narcotics and Controlled Drugs are licensed to do so. Licenses are issued on an annual basis with all licenses expiring on December 31 of the year in which they are issued. Before a company is granted a Narcotic or Controlled Drug license, it must meet certain standards. These include providing adequate security facilities for the storage of supplies and the employment of qualified personnel to supervise and be responsible for transactions. Licensed dealers may only release Narcotic or Controlled Drugs to authorized persons under specified conditions. Records must

be maintained over transactions and stock. These records are subject to inspection by pharmacist-inspectors employed by the Bureau of Dangerous Drugs, Health Protection Branch. In addition, dealers must submit monthly returns to the Bureau of Dangerous Drugs.

PHARMACISTS

Regulations of the practice of pharmacy in Canada is a provincial responsibility, governed by a licensing body in each of the ten Provinces. Therefore, when a pharmacist becomes registered with his provincial licensing body and is entitled to practise his profession, he automatically assumes certain privileges and responsibilities with respect to Narcotic and Controlled Drugs. Medication may only be released on the strength of prescriptions issued by a practitioner. A pharmacist must also maintain records of goods received and sold. Reports covering prescriptions dispensed are submitted to the Bureau of Dangerous Drugs at two month intervals. Adequate security must be provided over stock. A pharmacist's stock and records must be available for inspection by one of the Bureau's pharmacist-inspectors during regular business hours.

PRACTITIONERS

Practitioners, as defined by law, include physicians, dentists and veterinary surgeons. As with pharmacy, the practice of these professions is governed by appropriate licensing bodies in each Province. As soon as an individual becomes registered with his provincial licensing body to practise medicine, dentistry or veterinary medicine, he automatically assumes certain rights and obligations under Narcotic and Controlled Drug Regulations. A practitioner may only prescribe or make Narcotic or Controlled Drugs available to patients under his professional care, where the drugs are needed as part of treatment he is providing. In addition, upon request a practitioner must provide to the Department, information concerning Narcotic or Controlled Drugs purchased, prescribed, or otherwise made available by him to patients. A substantial number of practitioners in Canada choose to purchase Narcotic and Controlled Drugs in their own name and dispense the medication directly to their patients rather than issue prescriptions. These "dispensing practitioners" must maintain security over Narcotics and Controlled Drugs held in their dispensaries and keep records over material provided to their patients. As with pharmacists and licensed dealers, their stock and records must be available for examination by one of the Bureau of Dangerous Drugs' pharmacist-inspectors during normal business hours.

HOSPITALS

The definition of hospital includes institutions that are operating primarily for the care and treatment of persons or animals suffering from disease or illness. For the most part, they are regulated by the Provinces. Narcotic or Controlled Drugs received by a hospital may only be made available to a patient receiving treatment (either as an in-patient or out-patient) and upon the strength of an order or prescription issued by a practitioner. A

person in charge of a hospital is obligated to ensure that adequate security is provided for the storage of Narcotic and Controlled Drugs within the hospital and that records which will account for medication purchased are maintained. Stock and records at a hospital are subject to examination during normal business hours by a member of the Bureau of Dangerous Drugs' inspection staff.

RESEARCHERS

If an individual wishes to undertake a research project involving administration to humans or animals of a specific Narcotic or Controlled Drug, he must apply to the Health Protection Branch for authorization to do so, and at the same time submit a protocol of his project. Each protocol is examined by a panel of non-governmental medical and scientific experts, who judge its value. The Branch supplies drugs needed for the research, either directly to the investigator, or by making arrangements for the investigator to obtain material from a legitimate outlet such as a licensed dealer or pharmacy.

RESTRICTED DRUGS

Drugs covered under Part IV of the Food and Drugs Act, (so-called Restricted Drugs) are hallucinogens which have no generally accepted place in the routine practice of medicine. Of the 16 drugs included in this category, only three (LSD, MDA, and LSD with phen-cyclidine (PCP)) are encountered in illicit circles with any degree of regularity. The vast preponderance of Restricted Drugs appearing in illicit circles in Canada are manufactured in clandestine laboratories, in this or other countries, and are not diverted from the licit market.

Because Restricted Drugs are not used in everyday medical practice, regulations concerning them do not provide for their distribution to medical practitioners for treatment purposes. Provision is made, however, for their distribution and use by medical investigators. Restricted Drugs for approved research projects are provided by Health Protection Branch. Medical investigators are obliged to exercise control over Restricted Drugs received for a research project; stock and records are subject to examination by a member of the Bureau of Dangerous Drugs' inspection staff.

SPECIAL PROBLEMS

Heroin and Methadone

In certain countries, heroin is prescribed by physicians for maintenance of heroin-dependent persons. Its use for this purpose is not prohibited under the terms of the Single Convention. In the United Kingdom, for example, authorized physicians, attached to drug treatment centres, may legally prescribe heroin to those who voluntarily register for treatment. In Canada, however, the drug is not available for this purpose. As a matter of administrative policy, Canada has prohibited the legal importation of heroin since 1955 in response to a resolution of the U.N. Economic and Social Council which urged member states to cease manufacturing or importing the drug.

Although the Commission of Inquiry into the Non-Medical Use of Drugs (the LeDain Commission) has recommended (3) that heroin should be available to authorized physicians to use in special cases, the Canadian Medical Association has registered strong opposition to any such proposal. In 1972, the Minister of National Health and Welfare indicated that the Government, after studying the LeDain proposal regarding heroin, and taking into account the abuse potential and likelihood of diversion of heroin to the illicit market, concluded it was opposed to legal distribution of the drug. Nevertheless, in view of the obvious need to consider all possible ways by which the current widespread use of heroin can be controlled, the value of heroin maintenance programs is still under investigation.

The synthetic analgesic methadone has in recent years been prescribed widely for the treatment of opiate dependency. Approximately two years ago widespread evidence began to appear that large amounts of methadone were being diverted from the legal to the illicit markets in Canada. This evidence included many instances of forged prescriptions, so-called "double doctoring", steadily escalating dose, "medical shopping", and permissive prescribing. As a result, regulations were enacted, effective June 1, 1972, whereby a practitioner can only prescribe methadone upon being authorized by the Minister of Health and Welfare to do so. Before a physician receives this authorization, he must provide details as to how the drug will be prescribed in his medical practice. This Legislation has been effective in that widespread abuse that was occurring with respect to methadone has been reduced substantially. At the same time, individuals who need the drug are able to receive it under proper treatment conditions. Before enactment of the Regulations in June 1972, there were three structured methadone treatment programs in Canada. At the present time, there are 30 accredited treatment units across the country, with 132 affiliated physicians, all using methadone under acceptable protocols filed with Health Protection Branch. There obviously is room for considerable improvement in our ability to attract narcotic-dependent persons to proper treatment programs.

Amphetamines, Phenmetrazine and Phendimetrazine (Designated Drugs)

There has been considerable concern in recent years about widespread abuse of amphetamines and related stimulants. This abuse involves drugs from two sources: those legally prescribed (mostly to adults) and those illicitly manufactured in clandestine laboratories and distributed primarily to young people. The amounts of amphetamines prescribed by practitioners have dropped considerably in recent years. In 1966, for example, 1040 kg. of amphetamines (amphetamine plus methamphetamine) were available for medical use in Canada; in 1970 this amount had dropped to 309 kg. and in 1971 was just under 300 kg. Nevertheless, in the light of considerable evidence of continuing abuse of legally prescribed amphetamines, and the related drugs phenmetrazine and phendimetrazine, regulations were enacted, effective January 1, 1973, which require that a practitioner can only prescribe a Designated Drug for certain specific medical conditions. These conditions, which were arrived at by panels of non-governmental medical experts, are as follows:

- (a) In humans: (i) narcolepsy, (ii) hyperkinetic disorders in children, (iii) mental retardation (minimal brain dysfunction), (iv) epilepsy, (v) parkinsonism, or (vi) hypotensive states associated with anaesthesia; or
- (b) In animals: (i) depression of cardiac and respiratory centres.

As originally enacted, the Regulations required practitioners to obtain the opinion of a medical consultant if Designated Drugs are prescribed for more than 30 days, and to notify the Health Protection Branch when a Designated Drug was prescribed. In the 9 months since the Regulations came into force, use of Designated Drugs has markedly decreased. Importation, sales and prescription data all indicate that use of amphetamines, phenmetrazine and phendimetrazine has decreased by at least 90 per cent. Accordingly, we have moved to reduce the administrative workload on physicians, while retaining essential controls over these drugs. This will be accomplished by omitting the need to notify Health Protection Branch when a Designated Drug is prescribed, and by no longer requiring the opinion of a medical consultant if the drugs are prescribed for long-term use. Physicians will still be permitted, however, to prescribe Designated Drugs only for approved conditions. Needless to say, these conditions will periodically be re-examined to ensure they are in accord with good medical practice.

Phencyclidine

Phencyclidine was synthesized by the Parke, Davis Company in the late 1950s, and was originally developed for use as an anaesthetic in humans. It became apparent that undesirable side effects rendered it unsuitable for this purpose, and it was subsequently marketed as a veterinary anaesthetic. One of its chief uses has been in the immobilisation of large potentially ferocious wild animals in surveys of their physiology, migratory patterns, group behaviour, and so on.

In the past few years use of the drug has taken a disturbing direction. As a result of its hallucinogenic properties and sedative effect, phencyclidine has increasingly been available on the illicit market in Canada. Typically the dosage form offered for sale has been a gelatin capsule containing a few mg. of phencyclidine plus diluents. The street name is "the peace pill" or PCP.

The number of PCP samples analyzed in Health Protection Branch laboratories grew from 101 in the fiscal year ending March 1970 to 426 in the year ending March 1973. The distribution is of course most widespread in the large urban centres.

In late 1971, along with marked expansion of use of PCP, came another disturbing trend: the mushrooming use of a combination of PCP with LSD, with Montreal becoming the focal point for its use. In the year ending March 1973, the Canada-wide use of the combination was almost as extensive as PCP alone, with over half the cases in Montreal. The combination is found as capsules or tablets and typically contains 1-2 mg. PCP and 25-120 mcg. LSD.

This trend is continuing in the present fiscal year with Montreal's figures already twice those of last year at the same time. The combination of LSD and PCP is obviously of clandestine production. As with LSD, the pure PCP is thought to be all of clandestine origin, since no manufacturer is authorized to sell a solid oral dose form in Canada. All material legally imported is in the form of a solution for parenteral administration. It is known that PCP is readily synthesized from easily available starting materials. As a result of these concerns, phencyclidine now has been placed on the Schedule to the *Narcotic Control Act*. Although it is not a narcotic, it is considered to require narcotic-level controls, in order to deal effectively with the illicit traffic.

Cannabis

In 1972, the LeDain Commission presented its views on the legal status of cannabis (2). A majority of Commissioners recommended there should be no prohibition against the simple possession of cannabis, and penalties associated with importing and trafficking should be reduced. One Commissioner recommended a policy of legal distribution of cannabis, while yet another recommended that the prohibition of the possession of the drug should be maintained, but penalties for unauthorized possession should be reduced markedly from those currently in force.

The Federal Government's policy on cannabis was announced by the Minister of National Health and Welfare, after the Government had examined the report of the LeDain Commission. The salient features of the policy are as follows:

1. The Government has no intention to legalize possession of cannabis in any form, nor does it intend to legalize the cultivation of cannabis for personal use.
2. The Government recognizes the need to amend the laws respecting cannabis to reduce the impact of the law on the offender involved with possession of the drug, while retaining stiff penalties against those who traffic in, cultivate or import cannabis and are the major instruments by which the drug is spread throughout our society.
3. The Government intends to transfer all offences and controls relating to cannabis from the Narcotic Control Act to the Food and Drugs Act or other appropriate federal legislation.
4. The Government will reduce the consequences of certain unlawful acts relating to cannabis.

In announcing Government policy concerning cannabis, the Minister voiced concern about: (a) the possible effects of the drug on the maturation of adolescents; (b) the possibility that long-term heavy use may result in significant mental disorder, or influence the operation of automobiles and other machinery; and (c) the possible relationship between cannabis and the increase in multiple drug use.

The Government has taken action to remove the necessity in certain cases for the imposition of criminal records on persons charged with possession of cannabis, and to permit the removal of such records from persons already convicted.

The *Criminal Law Amendments Act* that came into force on July 15, 1972, makes it possible for judges, instead of convicting an accused person, to direct that he be discharged absolutely or under probation conditions. If a person receives this kind of discharge he is not considered to have been convicted of the offence.

The Federal Department of Justice has instructed all criminal prosecutors in cannabis cases to urge the Courts to apply absolute or conditional discharge in cases of possession of cannabis if there is no concurrent conviction for other offences and if the accused person has no previous criminal record.

Under the Criminal Records Act, anyone convicted of offences concerning cannabis is already eligible for pardon after appropriate periods of good behaviour.

Benzodiazepine Minor Tranquillizers

Certain psychotropic drugs, in particular the so-called benzodiazepine minor tranquilizers, are energetically advertised and promoted to the medical profession in this and other countries. Diazepam has for the last several years had the highest sales volume of

any prescription item in Canada, far out-distancing its nearest competitor, an oral contraceptive. A popular brand of diazepam (Valium) has now become the leading cause of accidental poisoning reported to our Poison Control Centres. During the year ending March 31, 1973, over 3.4 million prescriptions were filled for diazepam in Canada. Its "sister" drug, chlordiazepoxide, was prescribed over 780,000 times in the same period.

Although the benzodiazepines have demonstrated value in medical practice, it is fair to say that the aggressive marketing tactics utilized by the drug industry have contributed significantly to their widespread use. Some observers have concluded these drugs are often prescribed for use in situations calling more for long-term social adjustment than for a temporary chemical crutch. Others have suggested that some physicians find it easier to write prescriptions than to take the time and effort to provide advice. On the other hand, overworked medical practitioners face real dilemmas in attempting to prescribe psychotropic drugs responsibly and rationally. Patients often demand medication, perceiving it to be a magical way out of their troubles. It must not be forgotten, too, that although the use of psychotropic drugs cannot permanently alter undesirable social situations, and in that sense is palliative only, mental anguish causes at least as much suffering as physical pain and may have somatic consequences. Rational, responsible use of psychotropic drugs to relieve even ill-defined psychological disorders should not be considered as a craven surrender to human weakness. There is nothing really noble about needless suffering.

Although as noted above, the benzodiazepines have a legitimate place in clinical medicine, it often is suggested that their present level of use is in excess of the most generously estimated medical needs. If this is true (and there are those who would dispute it), what can (or should) Government do about it? Some physicians might argue that Government has no right to examine medical use of psychotropic drugs, and that any attempt to do so represents an intolerable intrusion on the autonomy of the medical profession. Such a position, however, cannot be sustained on logical grounds. The prescribing of drugs with social consequences clearly is of concern to society in general. It seems reasonable, therefore, that physicians should be accountable to society for acts they commit which have social consequences. Government has for many years demonstrated its willingness to protect society as a whole, even if that involves some interference with the actions of specific special interest groups.

Although Government clearly has not only the right, but also the obligation to examine medical use of psychotropic drugs, including the minor tranquillizers, it does not follow that Government regulatory action is always (or even often) the best way to control overprescribing of them. Therapeutics is still a very inexact science, and the intrinsic inability of the law to adequately take into account the unique needs of specific patients is at least potentially dangerous. Furthermore, laws aimed at controlling the excesses of a small minority of physicians may well work undue hardships on the vast majority of those who prescribe the drugs involved in a reasonable way. It follows, therefore, that Government's action to control overprescribing must be flexible and as non-bureaucratic as possible. It should depend heavily, wherever possible, on self-regulation by the medical profession. Ultimately, action to rationalize the prescribing habits of physicians as a whole must originate within the medical profession itself, by means of improved pre-and post-graduate education and increased professional responsibility. Improved two-way communication between Government and the medical profession obviously is desirable.

Over-the-Counter Drugs

Occasionally, we learn of abuse of over-the-counter drug products containing psychotropic ingredients. Usually, such abuse is spotty and on a small scale. When such occurs, Government has two alternatives: to put the drug under tighter regulatory controls, or to carry out non-regulatory action to control the problem. We have used both procedures, depending upon our perception of the extent of the problem. Before regulatory action is taken, however, its costs as well as benefits must be taken into account. For example, placing an over-the-counter drug on the Schedule to the Narcotic Control Act, changes its status to that of a prescription drug, as well as requiring extensive controls on the part of manufacturers, dealers, physicians, pharmacists and hospitals. The effects of such action on the already heavily burdened health-care delivery system, as well as on patients themselves, must be balanced against the reduction of abuse of the drug.

THE EFFECTIVENESS OF CANADIAN LEGAL CONTROLS
OVER PSYCHOTROPIC DRUGS

It is difficult to determine the extent to which Canadian legislation has provided effective control over psychotropic drugs. All but the most ardent proponents of law and order would admit that legal procedures are not the only effective way to control drug use. The vast majority of authorities agree that the law is but one part of what must be a multifaceted control program. Drug control programs based on simplistic law and order approaches have in general been ineffective and even counterproductive.

On one hand, effective legal control over psychotropic drugs has been achieved in this country. In Canada, unlike many other countries, there is remarkably little diversion of drugs from the legal to the illicit markets. Furthermore, control over psychotropic drugs which have a legitimate place in medical practice has been achieved without imposing inordinate administrative burdens on the health professions or denying patients drugs needed for treatment. On the international front, too, Canada has fulfilled her obligations, and is highly respected by other countries for effective control over drugs in international commerce.

But of course, there is much more to it than that. LeDain *et al.* (2) have pointed out that we can control the use of drugs by altering their availability or the demand for them. Availability can be influenced in two ways: by criminal law prohibition or administrative regulation. In Canada, the availability of certain drugs, such as heroin or cannabis, has been controlled by legal prohibition. The availability of other drugs, such as morphine or methadone, has been controlled by regulation.

Demand for drugs is influenced by many factors, including social pressures, personal choice and so on. Legal prohibitions against specific drugs undoubtedly affect the demand for them, to a certain extent. It is obvious, however, that legislation has not been outstandingly successful in eradicating the demand for many psychotropic drugs, of which cannabis is merely one example.

Effective legal control over the use of drugs, whether achieved by manipulation of availability or demand, depends to a large extent on the public perception of the laws governing drug use, and the willingness of the citizenry to obey them voluntarily. Laws which are not perceived by the majority of the populace as being morally just are not

likely to be effective. At least they must not be considered to be so unjust as to be unworthy of voluntary compliance.

Any consideration of the effectiveness of Canadian drug laws obviously must take into account the personal and social costs of the law as well as the benefits which accrue to the individual and to society from its administration. It is at this point — the determination of the balance between benefits and costs — that there is so much honest difference of opinion between people of good will.

To many people, discussions about drug laws quickly become highly emotional. Our perceptions of what should constitute society's response to drug use are deeply colored by our own highly personal feelings about ourselves and those around us. Puritanical views that pleasure is somehow sinful, parental feelings of guilt over children who seemingly have abandoned the standards of their parents, rationalization by adults over their own drug use, a longing for the supposed clear-cut standards of the past, our own self-image, a fear of the unknown future in a world which seems to many to be tumbling out of control — all combine to cloud our minds and make objective reasoning about drug laws difficult. Efforts to make rational judgments about the cost/benefit ratios involved are seriously hampered by lack of scientific knowledge concerning the effects of drugs on the individual or society, and are further impeded by varying views about what constitutes the most desirable state of society. Decisions almost always have to be made in the absence of the definitive data normally considered essential in making complex decisions.

It is hardly surprising, therefore, to see the "experts" divided in their views about what constitutes rational social policy in the drug control field. The recent three-way split in the LeDain Commission over what should be the legal status of cannabis is but a reflection of the difficulty an open pluralistic society has in reaching consensus about the best solution to a problem which combines complex scientific, medical, political, moral, legal and economic factors.

It is clear that effective drug laws must take into account the ethical and moral standards of contemporary society. For that reason, their form and content must, in my view, be determined by society itself, through its elected representatives, the Parliamentarians. In the drug control field as in many other aspects of life, we get what we deserve.

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Some Factors Involved in the Increased Prescribing of Psychotropic Drugs

Ruth Cooperstock¹

We have sensitized ourselves to recognize the signs of anxiety, and we have been taught that the signs of anxiety are *symptoms*. We have been encouraged to the fallacious value of a total avoidance of anxiety as a goal of life; we have been led to believe that complete freedom from anxiety would be the distinguishing characteristics of an adjusted life.

William Schofield

Psychotherapy, the Purchase of Friendship, p. 152.

A recent autobiography describing a childhood on the Canadian prairies says about the local doctor, "His function was pretty much confined to delivering babies and making the diagnoses which resulted in the dread QUARANTINE signs being nailed to one's door. I suppose, given our lonely situation and the primitive pharmacology of the twenties, there wasn't much a general practitioner could do except sit by bedside looking grave or wise." (1). Fifty years later there is little need at most consultations for the physician to look grave, though it is still helpful to look wise; he now has his prescription pad at the ready and at over two-thirds of all consultations prescribes medication of some kind.

Whether one examines United States, Canadian or United Kingdom figures on prescription drug use one reaches the same conclusion. The absolute numbers of prescriptions are increasing on a yearly basis and psychotropic drug prescriptions as a proportion of all prescriptions are increasing at a striking rate. Parish documents this clearly for England and Wales, as seen in Table I. In the six years from 1965 to 1971 the total number of prescriptions in the United Kingdom increased from 244.3 million to 266.5 million, even though prescription charges were reinstituted in 1968. Psychotropic drugs,

¹Addiction Research Foundation, 33 Russell Street, Toronto, Ontario, Canada M5S 2S1.

however, rose from 38.5 to 48.0 million over the same period. Thus, as a proportion of all prescriptions, the psychotropic drugs rose from 15.8 per cent to 18.0 per cent of the total dispensed. For sales within the United States, Muller (2) gives the proportion of psychotropic drugs to all drugs as 28.3 per cent during 1969.

TABLE I

PSYCHOTROPIC DRUGS AS A PROPORTION OF ALL PRESCRIPTION DRUGS
ENGLAND AND WALES (1965-1971)^a

Year	Total No. of Prescriptions (Millions)	No. of Psychotropic Prescriptions (Millions)	Psychotropic as % of Total
1965	244.3	38.5	15.8
1966	262.0	40.9	15.6
1967	271.2	45.3	16.7
1968	267.4	46.5	17.4
1969	264.2	46.2	17.5
1970	266.6	47.5	17.8
1971	266.5	48.0	18.0

^aBased on Parish, P. A., "Psychotropic Drug Prescribing Trends and Influences", Appendix II, p. 101, in Symposium on the Prescribing and Use of Psychotropic Drugs, July 1st-2nd, 1972, University of Wales, 76-103.

It is apparent from many sources, however, that not all psychotropic drugs have increased in popularity. Consumption of some has fallen off, both relatively and absolutely, while that of other psychotropics has increased at a startling rate. Since there are no published North American data comparable to those supplied by the Department of Health and Social Security for England and Wales, we have shown the data on psychotropic drugs in England and Wales separately in Table II. Information from more limited studies in Canada and the United States is used to make up Table III² which presents data that parallel the periods covered by the English material. Table II shows a marked decline in the prescribing of stimulants; they dropped from 13.9 per cent of all psychotropics in 1965 to 6.1 per cent in 1971. There are indications that the prescribing of this class of drugs has declined recently in North America as well, but Table III shows only a very slight drop from 15.9 per cent to 14.6 per cent.³ The figures for the other classes of drugs are remarkably similar for the three countries. In England and Wales the antidepressants

²These studies are all based on analysis of prescriptions. The ARF study utilizes a 10 per cent sample of all prescriptions dispensed in Metropolitan Toronto over two one-week periods during April and October, 1965-6. Levine's data come from a national audit of prescriptions in pharmacies conducted by Gosselin and Co. The last series of figures, titled Green Shield, are based on a full year's prescriptions for approximately 40,000 families covered by a prescription insuring agency located in Southern Ontario.

³Great caution is required in drawing inferences from Table III about changes in prescribing over time as the three studies covered by this Table are based on quite different populations. The data for Toronto and for Southern Ontario are more comparable because they reflect prescribing by Canadian physicians in the same province and to largely urban populations.

TABLE II

PERCENTAGE DISTRIBUTION OF PSYCHOTROPIC DRUGS — ENGLAND AND WALES (1965-1971)^a

	1965	1966	1967	1968	1969	1970	1971
Psychotherapeutic Agents:							
Antidepressants	8.9	9.6	10.8	11.5	12.6	13.5	15.0
Tranquillizers	28.4	29.5	32.3	34.5	35.4	36.5	38.4
TOTAL	37.3	39.1	43.1	46.0	48.0	50.0	53.4
Stimulants	13.9	12.8	10.8	8.6	8.0	7.3	6.1
Sedatives and Hypnotics:							
Barbiturates	41.9	41.0	35.3	32.8	30.3	27.5	24.4
Non-barbiturates	6.9	7.1	10.8	12.6	13.7	15.2	16.1
TOTAL	48.8	48.1	46.1	45.4	44.0	42.7	40.5
TOTAL	100	100	100	100	100	100	100

^aBased on Parish, P. A., "Psychotropic Drug Prescribing Trends and Influences", Appendix II, p. 101, in Symposium on the Prescribing and Use of Psychotropic Drugs, July 1st-2nd, 1972, University of Wales, 75-103.

rose steadily from 8.9 per cent in 1965 to 15.0 per cent in 1971. These figures for antidepressants can be contrasted to 6.8 per cent in Toronto in 1965 and to 13.4 per cent in Southern Ontario in 1971. Sedatives and hypnotics showed a steady decline everywhere though at a lower rate of decrease in England and Wales than in Canada. It is with the tranquillizers that the great leap has occurred. The Canadian and United States data suggest a slight decline in the proportion of major tranquillizers, dropping from 10.2 per cent in 1965 to 8.9 per cent in 1971, while the minor tranquillizers have increased from 22.7 per cent of the market in 1965 to 36.2 per cent only six years later.

The major and minor tranquillizers are not shown separately in Table II. However, from another source (3) we find that the prescriptions for all tranquillizers in England and Wales rose from 10.8 million in 1965 to 17.2 million in 1970. The rise was largely due to a 110 per cent increase in the prescribing of minor tranquillizers, almost solely the benzodiazepines. By 1970 Librium and Valium alone accounted for 63 per cent of all tranquillizer prescriptions. Other tranquillizers excluding these two rose by only 25 per cent over the same period.

The remainder of this paper will discuss some of the many factors accounting for this sharp rise in the use of anti-anxiety agents and, to a lesser extent, the antidepressants.

TABLE III

PERCENTAGE DISTRIBUTION OF PSYCHOTROPIC DRUGS IN
CANADA AND THE UNITED STATES

	A.R.F. ^a 1965-1966	Levine ^b 1967	Green Shield ^c 1970-1971
Psychotherapeutic Agents:			
Antidepressants	6.8	8.6	13.4
Major Tranquillizers	10.2	9.5	8.9
Minor Tranquillizers	22.7	34.4	36.2
TOTAL	39.7	52.5	58.5
Respiratory and Cerebral Stimulants	15.9	15.4	14.6
Sedatives and Hypnotics	44.4	32.1	26.9
TOTAL	100	100	100

^aCooperstock, R., and Sims, M., "Mood-Modifying Drugs Prescribed in a Canadian City", Addiction Research Foundation, 1970, Substudy 2-31 & 29-70, Table 8-4, 84-85.

^bLevine, J., Statement on "The Nature and Extent of Psychotropic Drug Usage in the United States", presented before the Subcommittee on Monopoly of the Select Committee on Small Business, U.S. Senate, July 16, 1969, Chart 2, 8A.

^cData supplied to the Addiction Research Foundation for 1970-1971 by Green Shield Prescription Services, Inc., Windsor, Ontario.

THE POPULARIZATION OF MENTAL HEALTH INFORMATION

A few years ago it was the professional journals, women's magazines and the women's page in newspapers that carried information on health issues, especially mental health. Today, prime time television plays, newspapers, radio, magazines, have opened the human psyche to public scrutiny. As one instance, the National News on television on the opening day of school across Ontario featured, instead of the usual pictorial representation of youngsters on their first day of school, an interview with the Head of the Department of Psychiatry at a large children's hospital. The interview dealt with the problem of school phobia, its symptoms, the distinction between school phobia and truancy, and the recommended treatment. This is but one of the myriad examples of the attempt to bring into public consciousness problems of mental health and illness. The increased level of educational attainment in recent years encourages this type of interview on a national news broadcast.

There is little "scientific" evidence one can offer on the short or long term value of this trend. We can only speculate as to the relationship between this heightened public awareness and the use of psychotropic drugs. We will discuss some of the ways the pharmaceutical industry has redefined illness for the medical profession who transmit their concepts of health and disease to their patients. However, it may be of equal importance to ask what effect this trend to publicize mental health concepts and information is having on the public. Does it, as we would suspect, tend to make the public more conscious of the relationship between their physical and emotional state; more attuned to their 'feelings'; learning to be more 'introverted'?

In his epidemiological studies Hinkle attempted to identify and distinguish the characteristics of frequently ill workers, as opposed to those who were seldom ill. His observations may be relevant here. The frequently ill tended to take things more seriously, be more introverted, and show greater awareness of their own emotional difficulties (4).

Studies which enquire about general health problems tend to find an extremely small proportion reporting no health problems or symptoms. Wadsworth *et al.* (5) found less than 5 per cent of their sample of urban residents with no complaints. Dunnell and Cartwright (6) found 9 per cent of a random sample of adults in Great Britain reporting no symptoms. In fact, the average number of symptoms reported was 3.9. These figures indicate little about illness behaviour, about the decision to see a doctor, about the adoption of the sick role.

One can only wonder whether this increased awareness of one's physical and emotional self has led to an absolute increase in perceived illness (as Hinkle's findings might suggest), whether it has led some segments of the population to search out extra-medical coping devices for their ills, or whether it has legitimated the seeking of help on the part of the ill, lonely, discomforted.

Kessel (7) has observed that "the role of the doctor, as seen by the patient, is changing. It is changing more rapidly than the role of the doctor, as seen by the doctor". This may well be the explanation for the common complaints of general practitioners that they see too much "trivia", that patients waste too much of their time. Cartwright (8), Mechanic (9), and Cooperstock (10), in studies in England and Scotland all found a high proportion of physicians complaining of "trivial" consultations. For example, Cartwright found one-third of her physicians spontaneously mentioning unnecessary consultations about trivial complaints in response to a question on frustrations in general

practice. Mechanic found 59 per cent of his sample reporting that more than a quarter of all patient visits were for trivial reasons while Cooperstock found 51 per cent reporting this.

PHYSICIANS' PERCEPTIONS OF PATIENTS' SYMPTOMS

To further understand what these physicians perceived as the common problems they encountered in practice, Cooperstock asked a sample of Scottish physicians to specify the three symptoms they saw most frequently in men and women of different age groups.⁴ Table IV documents the large proportion of emotional disorders, of vague complaints that the physician perceives are presented to him on an ongoing basis. Since psychotropic drugs are typically dispensed in response to symptoms rather than to a diagnosis⁵, it is hardly surprising they are prescribed in such quantities. Sampling surveys (11) have established women aged 40-59 as the highest consumers of psychotropics; they also have the highest proportion of "mental disorders". We may also note the higher proportion of women perceived as presenting vague symptoms such as headache, vertigo, fatigue, lassitude. The high proportion of males with gastro-intestinal disorders may well be the male counterpart of women with mental disorders and vague complaints.

At this point it would be extremely difficult to separate cause and effect in relation to the changes in prescribing. We have thus far suggested that the population at large is increasingly aware of the relationship between their physical and psychological states and that physicians report seeing a high proportion of symptoms which could result in a prescription for a psychotropic drug. Perhaps a third factor which has set the physician's hand in motion toward his prescription pad has been the advertising of the pharmaceutical industry.

THE ROLE OF ADVERTISING

Psychotropic drugs have recently appeared in advertisements more frequently than would be expected from their current share of the prescription drug market. Seidenberg (12)⁶, in his analysis of the *Journal of the American Medical Association* in 1969, found that 32 per cent of the advertisements were for psychotropics, and in *Hospital Medicine* the proportion was 37 per cent. Prather and Fidell (13) found this figure to be 40 per cent in the journals they studied over a recent five year interval.

Lennard *et al.* (14), Rogers (15), and others have clearly illustrated the variety of ways in which the pharmaceutical industry is attempting to redefine a wide range of human experiences and behaviours as medical problems requiring psychotropic drug inter-

⁴The question read, "Thinking back over your experience in general practice, what three *symptoms* have you found most commonly presented by the following patients: (omitting pregnancy and respiratory ailments)." Spaces were provided for each of the six groups shown in Table IV.

⁵M. Marinker noted "the doctor prescribes psychotropic drugs in order to be able to make psychiatric diagnoses." Reported in *The Medical Use of Psychotropic Drugs*, Supplement No. 2, Vol. 23, 1973, *The Journal of the Royal College of General Practitioners*.

⁶In testimony before the Subcommittee on Monopoly of the Select Committee on Small Business of the U.S. Senate, Part 2, Advertising of Proprietary Medicines, 1971, p. 551, Dr. Seidenberg explained that the paper on drug advertising that he had submitted to both the *Journal of the American Medical Association* and the *Journal of the American Psychiatric Association* had been rejected by the two journals. It was accepted for publication by *Mental Hygiene*, a journal which accepts no drug advertisements.

TABLE IV

PERCENTAGE DISTRIBUTION OF MOST FREQUENT SYMPTOMS SEEN BY GENERAL PRACTITIONERS: BY AGE AND SEX OF PATIENT

Systemic Classification	Females				Males				Total
	20-39	40-59	60+	Total	20-39	40-59	60+	Total	
Genito-Urinary	29	29	9	23	1	2	15	6	14
Respiratory	3	—	5	3	9	13	17	13	8
Circulatory	—	2	11	4	—	13	20	11	7
Musculo-Skeletal	5	12	21	12	10	17	19	15	14
Gastro-Intestinal	2	2	6	3	24	20	9	18	11
Accidents and Injuries	—	—	—	—	21	8	—	10	5
Mental Disorders	23	31	24	27	21	15	9	15	21
Anxiety	9	7	5	7	12	6	2	7	7
Depression	4	11	9	8	2	3	2	2	5
Others	10	13	10	12	7	6	5	6	9
Social Problems	4	2	2	2	2	1	1	1	2
Miscellaneous	34	22	22	26	12	11	10	11	18
Lassitude, Fatigue	11	9	9	10	1	5	4	3	6
Vertigo, Headache	9	4	8	7	1	2	2	2	4
Other Symptoms	14	9	5	9	10	4	4	6	8
TOTAL: Per Cent # Responses	100 (132)	100 (134)	100 (131)	100 (397)	100 (127)	100 (124)	100 (123)	100 (374)	100 (771)

vention. Examples of some of the conditions specified in the advertisements include patients distressed by 'tedious' tasks and patients bothersome to physicians or to their families. Since these experiences have not yet been clearly labelled as specific disease entities, the emphasis in virtually all advertisements is on the treatment of symptoms.

A study of drug advertisements in the two leading Finnish medical journals during the years 1959, 1965, and 1971, demonstrates the cross-national similarities of pharmaceutical advertising (16). Over the interval studied the advertisements became increasingly general, particularly those for minor tranquillizers. By 1971 only one third of the advertisements for the psychotropics gave an 'illness' as an indication for use. In contrast to the major tranquillizers, considerably more space was devoted to pictorial material in the advertisements for minor tranquillizers.

With the non-medical indications for use of psychotropics increasing at a rapid rate in advertisements, we should be aware of an important consequence of this phenomenon. It appears that the more general the content of the advertising and the more it departs from the area of expertise of the industry, the more it reflects and expresses the popular misconceptions of the human situation in the modern world. This is well illustrated by both Seidenberg (12) and Prather and Fidell (13). Both papers discuss the image of women presented by these advertisements for psychotropics.

In a content analysis of advertisements in three medical and one psychiatric journal in the United States, Prather and Fidell document some of the biases in the advertisements for psychotropic drugs in particular. The authors show the clear relationship between type of illness and sex of patient. They found a disproportionate number of women pictured as suffering from emotional illness and too few women shown suffering from somatic disorders. Men were commonly portrayed as needing these drugs as a result of work pressures; women were simply shown suffering from diffuse anxiety and tension.⁷

It would appear that the industry is attempting to convince the physician-consumer that new, non-illnesses require therapeutic intervention. It is probably the case that a high proportion of the psychotropic drug advertisements reflect and reinforce values already held by the physician. Many advertisements also attempt to play upon the anxieties experienced by some physicians. For example, a recent advertisement for Stelazine⁸ pictured six photographs of the same unhappy looking woman with the accompanying text, "You've talked. . . You've listened. . . But here she is again". In other words, at the moment the physician can no longer cope with a complaining or demanding patient or is overwhelmed by her, the only alternative is tranquillization.

Marinker (17) discusses the problem of boundaries in general practice: boundaries between art and science as well as the boundaries between the various disciplines subsumed within general practice. He points out that increasingly it is "between the disciplines of physical pathology, psychology and sociology where the general practitioner constructs his diagnostic models". It is on the basis of these models that decisions regarding prescribing are ideally made. Advertisements in medical journals, however, increasingly seem to obliterate and also attempt to redefine these boundaries. For example, a recent two page advertisement for Mellaril⁹ shows a full page photograph of a rather dejected but pleasant looking young man leaning against a tree. Under the picture is a bold type caption, "The Outsider". This is the only large print in the advertisement besides the

⁷ It is also of some interest that in this advertising, women were never portrayed as therapists, only as patients.

⁸ *The American Journal of Psychiatry*, March, 1973, p. A47.

⁹ *Archives of General Psychiatry*, May, 1973, pp. 700-701.

name of the drug. The implication of this linking of the drug name with the sociological term is that *any* outsider (meaning deviant) requires medication. The finer print that describes Mellaril as an anti-psychotic agent suggests the man has just been released from a psychiatric hospital. This additional information further reinforces this concept, linking outside-deviant, hospitalization, and the necessity of drug therapy.

In a discussion of the role of pharmaceutical advertising, Teeling-Smith (18), Director of the Office of Health Economics in England, asks, "Are we not generally agreed that the medical profession gets the advertising it deserves? Is it not up to the profession to bring pressure to bear on the pharmaceutical industry to make changes?" These questions would sound more naïve if they were asked by someone less knowledgeable and whose organizational support was independent of the pharmaceutical industry. One might counter these questions with another one: would the pharmaceutical industry use these advertisements if the profession were knowledgeable enough to evaluate them?

A general practitioner-researcher (19) concerned with adverse reactions to psychotropic drugs commented at the same meeting, "As I look at the current advertisements for these drugs I cannot but feel some shame; partly I am disturbed that the pharmaceutical industry should use advertisements more suitable for cosmetics than for drugs, but mainly I am ashamed that such advertisements should be successful in influencing members of a learned profession."

Perhaps because of its high visibility, advertising has received more attention than other facets of activity on the part of the pharmaceutical industry. There are, however, innumerable other ways that the industry influences opinions, both directly and indirectly, and some of these warrant attention.

THE EFFECT OF THE INDUSTRY IN SPHERES OTHER THAN ADVERTISING

In Great Britain there is one detail man for every seven general practitioners (3); in the United States there are now more than 21,000 detail men. Total marketing costs are estimated at \$4,000 per physician per year, and the industry spends \$1.2 billion per year on advertising and promotion, which represents one-fourth of their dollar volume of drug sales (20).¹⁰

Aside from the pharmaceutical representatives, one should not overlook other areas of financial largess on the part of the industry directly aimed at the medical profession. A higher proportion of the income of the American Psychiatric Association comes from advertising in its journal than from membership dues in the organization. The corresponding figures for the American Medical Association indicate that 43 per cent of its income comes from advertising and 33 per cent from memberships (12). Additionally, the industry supports lectureships, professional meetings and conferences, all varieties of dinners, cocktail parties and social events for physicians and medical students, even to the extent of purchasing the symbolic little black bag for fourth year medical students (22). The industry also conducts extensive market research studies in many countries; these findings are seldom publicized. Only this past year the Canadian Government has pro-

¹⁰Stolley *et al.* (21) have demonstrated quite clearly that the physicians considered by a panel of physician-judges to be appropriate prescribers tended to rely more on other physicians and journal articles for their information on therapeutics and were more critical of the pharmaceutical industry than the poorer prescribers. Good prescribers felt pharmaceutical representatives were poor sources of information on new drugs.

posed an end to the expensive habit of distributing free unsolicited drug samples to physicians.

An important and little publicized type of funding on the part of the industry is the support of research, particularly clinical trials of new drugs. Funding for research may come in the form of free supplies of drugs as well as actual money for equipment, laboratory assistants' wages, and so forth. Since many new drugs are only available from pharmaceutical companies and, since there is often great pressure on physicians in medical schools to publish, it appears unlikely that physicians interested in clinical trials could avoid some pharmaceutical support. One wonders what the effect of reporting negative findings might be for the researcher under these conditions. How widely are negative findings disseminated? Has any research ever been conducted on the difference between the findings reported by those doing clinical trials supported by industry funds and the results of government or university supported research? Were the research methods employed the same for the two groups? With no knowledge of funding, would judges evaluate the research as of equal substantive and scientific quality, including such matters as the adequacy of the kinds and numbers of subjects and controls used, the appropriateness of dosage, and so forth?

A more subtle form of influence could exert itself at a different level in the research process. Rather than directly affecting the methods employed or the reporting of findings, does funding influence the initial questions asked by a researcher? Every research worker must establish personal priorities for the research projects he or she chooses to conduct. How are these priorities determined? If an increasing proportion of the money for research comes from one source, will this result in a distortion of the range of problems selected for study?

Analysis of completed research suggests some answers to a few of these issues. As a case in point we will examine the literature on one aspect of psychotropic drug therapy: that relating to these drugs as adjunctive therapy for a variety of somatic disorders.

THE EFFECTIVENESS OF PSYCHOTROPICS AS ADJUNCTIVE THERAPY¹¹

It seems clear that many patients who exhibit symptoms of emotional disorder also tend to suffer from a range of physical disorders (23, 24). This would appear to support the widespread use of psychotropic drugs as adjunctive therapy. Parry *et al.* (11) have reported that this is now the primary use for these drugs in the United States. Levine (25) has taken the position that though psychotropic drugs are not primarily dispensed to persons with a psychiatric diagnosis, they are nonetheless prescribed appropriately when the physician's intent is examined. This position assumes that these drugs are given to individuals in whom anxiety or depression is a secondary feature of a somatic illness or that the illness may have set off an anxiety or depressive reaction which was neither an initial component nor causative. Levine contends that, in general, the psychotropics are used appropriately to allay anxieties which could exacerbate symptoms of, or delay recovery from, a wide variety of cardiovascular and gastro-intestinal disorders, among others.

Although there is a wealth of literature available on the use of these drugs in the treatment of anxiety, insomnia, and other symptomatology related to neurotic states, there is remarkably little research dealing specifically with the use of psychotropic drugs as adjuncts for a variety of somatic conditions.

¹¹The author wishes to thank Ms. Carol Corlis for her contribution to this section.

A review of 490 studies (2) on the effectiveness of the antidepressants found that, in general, the less rigorous the technique, the greater the improvement reported. In an effort to select better designed research, we have limited ourselves to control double-blind studies and case studies which reported more than a few cases.

The findings to be presented are based on an examination of the *International Pharmacological Abstracts* from 1964 to the present. Included are all studies with human subjects meeting the above criteria, involving psychotropic drugs used as adjuncts in treating illnesses with psychosomatic components such as hypertension, cardiac disorders, gastro-intestinal disorders, asthma, and others, as well as studies testing these drugs for their effectiveness in other illnesses and conditions, such as epilepsy, pregnancy, cerebral palsy, and tetanus.

A total of 12 control double-blind studies on the subject were located, and, of these, two did not describe the control groups used (26), and one tested a placebo against a combination drug rather than testing the two components separately as controls (27). Of the remaining nine studies, eight (28-35) indicated that the psychotropic drug was either equally effective as, or less effective than, some other mode of treatment which produced fewer side effects. The last study (36) demonstrated a superior response to diazepam over two standard reference drugs for short-term treatment of neuroskeletal disorders. However, in this study the most problematic symptom, 'limitation of motion', was not alleviated by any of the drugs used.

Of the case studies listed, only three utilized a sample of more than 15 patients and analyzed their data statistically. Of special interest, in view of the frequency of prescriptions, are the studies on gastro-intestinal and cardiovascular disorders. The research on the use of minor tranquillizers in the treatment of gastro-intestinal ailments provided an example of the difficulties encountered in evaluating this work. Wayne (37) tested Librax against a placebo, finding Librax more effective than the placebo in diminishing anxiety-tension, insomnia, abdominal pain and nausea, but no more effective in alleviating the following symptoms: diarrhea, flatulence, heartburn, indigestion. Another study on the use of Librax (27) analyzed differences in secretion rate but failed to utilize reference group controls for each of the components of Librax, thus making it impossible to understand the interaction effect of the components¹². Marino (26) also reports positive results with a combination of chlordiazepoxide and amytriptyline, but his control groups were not defined.

Case studies involving the use of MAO inhibitors in treatment of hypertension and hypotension have involved very few cases (38-40) and have concluded that the dangers far outweighed the advantages gained by their use. The only control study found on the treatment of hypertension was reported by Marino (26), but again his control group was not described.

Schumann's careful study published in Germany in 1970 (41) involved a sample of 186 myocardial infarction cases. He found the total mortality rate, and the first day mortality rate in particular, diminished with the use of diazepam administered at the time of, and immediately after, the heart attack. It must be noted that his study only involved administration of the diazepam during the actual acute phase. A recent French article on the use of MAO inhibitors in the treatment of angina (42) warns of the risk of masking the symptoms of angina with psychotropic drugs.

¹²It is worth noting that this was one of the rare studies found which attempted to build into the design anything beyond subjective patient reports of symptoms.

In summary, in the course of a literature search covering the last ten years in which we included only control double-blind studies and case studies utilizing 15 or more cases, we found little to support the use of psychotropic drugs as adjuncts in maintenance therapy of a variety of common physical illnesses. The studies which reported most benefit from the use of a minor tranquillizer, usually diazepam, involved emergency situations such as status epilepticus or myocardial infarction, in which the patient was given the drug intravenously for a brief period; the drug was then slowly terminated under hospital conditions of close observation. Most striking was the absence of studies testing the use of these drugs as maintenance therapy for largely psychosomatic ailments. It is not within the scope of our discipline to question the validity of the current prescribing practices but only to point out the lack of research findings to support this massive use of drugs.

SUMMARY AND CONCLUSIONS

In this paper we have attempted to specify and examine a few of the factors affecting the rapid increase in the prescribing of psychotropic drugs. Certainly other factors have been involved, such as the practice of repeat prescribing so eloquently described by Balint and his associates (43). The variables singled out include the increased self awareness of the public, a trend which has been accelerated in part by mass education and especially by the mass media; the change in the physician's perceptions of symptoms; the impact of advertising and other activities on the part of the pharmaceutical industry, and the paucity of adequate research which leaves doctors insufficiently informed.

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Economic Aspects of Medical Use of Psychotropic Drugs

Charlotte Muller¹

When considering policy formation over the selection of psychotropic drugs and the desirable level of their medical use, we must identify the circumstances in which use is justified. Appropriate medical, social, and economic criteria must be considered.

In setting about this task, one faces fundamental choices about the role of science within a service-oriented economic activity. Compassion may suggest the use of drugs to relieve human distress, and one may be sympathetic to the idea of using placebo effects to an acceptable end. But the use of either must include a sophisticated understanding of how the place and conditions of administration of psychotropic drugs influence success (1). Compassion however offers no solution to the problem of making a rational choice for there are too many factors to be considered, such as: possibly distressful side effects; neglect of alternative strategies to help the individual; the opening up of unintended and diffuse effects in society conducive to drug abuse; and the facilitating of deliberate diversion and abuse.

Furthermore, economic considerations are involved. The cost of psychotropic drugs represents resources that could be committed to other areas of human welfare. The self-interest of vendors in sustaining the market for psychotropic drugs serves as a signal that a doctor-patient situation nurtured by commercial efforts needs critical examination. Otherwise compassion and pragmatism will continue to be used to achieve the ends of interested others who remain offstage when doctor meets patient. We must ultimately consider how far it is necessary to modify industrial practices within a corporate

¹Center for Social Research, Graduate Center, City University of New York, 33 West 42nd Street, New York, N.Y. 10036.

economy in order to achieve more tolerable ends, and what methods of doing so offer most promise.

Interdisciplinary collaboration is called for to reveal the forces behind the decisions leading to a given pattern of drug use so that we may see more clearly what alternatives can be developed and how they can be attained. The task is challenging because numerous variables contribute at different stages of the lengthy process that culminates in the medical use of drugs. A simple search for statistical associations, even though they are obviously relevant, will not suffice as analytic effort.

Two economies are involved: the smaller economy of health services, and the larger economy in which the patient interprets the individual/society relationship with the resulting anxieties and psychic needs arising from stresses in this relationship. From the policy point of view the involvement of the larger economy opens up the range of policy variables that can be acted on to influence drug use. Even the pessimism one might feel about the difficulty of changing such factors as employment security, forced retirement, emulation and competition must be tempered by the realization that specific efforts to reverse risk factors are within the scope of social and medical services. This fact provides an important link between the two economies.

Economic factors that affect drug use patterns may differ from country to country. Differences may be traced to such factors as social roles of the sexes (2), retirement patterns, sick leave, insurance for drug costs, the structure of the drug market, accessibility of medical care, and generalist-specialist relations within medicine. Government regulatory policies also play a part. In the background, the level of industrial development helps define the occupational and social role of the two sexes, the distribution system for drugs, and so on.

SCIENCE, SOCIETY AND PRESCRIBED DRUGS

To understand trends in drug use one must also consider the role of science in the industrial economy. I take the risk of making some undocumented and perhaps arguable statements on this subject in order to call attention to the subtlety and variety of social influences on drug use under medical auspices.

In recent decades, various factors leading to a high level of medication converged. The public acquired an optimistic attitude about science and its potential. Vendors of products of technology nourished this attitude both to induce sales and to prevent regulation. With the optimism came a fear that the country would fall behind in the race of invention and discovery.

As new drugs were discovered, inadequate models were used for measuring pharmacological effects. The models failed to encompass all the aspects of the organism and the dynamic processes of reproduction and growth. An economic climate which emphasized short-term return on investment and quick turnover of drug entities would have no place for long-range, multifaceted study of sequelae. The experimental situations for valid study of drug effects called for large scale, even international organization. Medical treatment and a controlled environment made possible the survival of individuals despite multiple impairments and this perhaps made it harder to trace any harm to a specific drug. Market interests made government intervention necessary in order to check introduction of a new drug, but at the same time market power erected barriers to effective government action.

Reasons for Increased Drug Use

Modern industrial society tended to create frustrations for its members but not the capacity to tolerate them well. Consequently, in compensation people sought fast relief for frustration insofar as money could buy it in the medical market. A secular society had downgraded preachers but medical healers could take over the task of uplift of spirit, that is mood elevation. The indications for prescribing were broadened by recognition that mental symptoms could be explained by conditions of physical health. The book *Drug Evaluation* put out by the American Medical Association states that “depressive symptoms are common in patients with medical and surgical conditions” but notes that “most depressions are self-limiting and improve without specific treatment.” (3,p.257). These conditions became more prevalent owing to survival of the chronically ill: as more people gained access to medical care the conditions were brought to physicians’ attention, and the growing interest of medicine in the whole person (4) increased physicians’ awareness of the sick person’s emotionality. Some of the very drugs used to treat physical states provoked emotional difficulties. Anxiety, depression, lethargy and even personality change may be caused by drugs used in treatment of hypertension and other disorders (3b).

Broadened indications for prescribing also arose from those mental symptoms which have no clearcut psychiatric diagnoses, but are linked to stresses of industrial and white collar life. Some familiar types of distress were renamed in medical nosology to become mental symptoms.

Certain features of medical practice reinforced these various influences. For instance, medical specialization tends toward a high level of psychotropic drug use since adverse effects are easily lost from view and may lie outside the area of specialization.

Then too, search for information is costly to the doctor in terms of time, and solo practice sharply limits the most time-saving routes of unbiased information: one’s peers and the organization in which one works. Even doctors’ concern over addiction led to increased prescribing of certain drugs (in particular chlorpromazine) because they were believed to be non-addictive.²

Eventually, checks to excessive medication arose from the growth of science and its socioeconomic effects. Some of these influences were fairly direct. Opportunities for longitudinal study of accumulation of side effects improved. The thalidomide case led to more direct concern with fetal risk from drugs. The case of diethylstilbestrol (6a), administered during pregnancy a generation ago and recently associated with vaginal carcinoma in young women, is an example of such an effect that took many years to become manifest. Rules of market access for new drugs were made more strict in 1962.

More generally, accumulated side effects of industrial and urban growth and of the technological-commercial culture led to disillusionment with the gross national product as a measure of well-being.

Many persons came to distrust commercial values, including in this distrust the medical care system, which failed to deliver mass service while it responded to the class market. Parts of the women’s movement withdrew from traditional health care. Diet regimes attracted new followers. Finally, drug abuse tragedies forced understanding of a possible connection between a drug-taking straight society and youth problems with drugs (7).

²Subsequently both physical dependence on and tolerance to chlorpromazine were observed (5a).

Nevertheless the volume of medications per capita has continued to rise in recent years (8), and a large portion of this is attributed to the central nervous system drugs. (Table I shows figures on this class of drugs from the United States, Canada, and the United Kingdom.)

TABLE I
RELATIVE IMPORTANCE OF VARIOUS TYPES OF CENTRAL NERVOUS
SYSTEM DRUGS

	Cooperstock*	Parish†
Period:	1965-66	1970
Population:	Toronto dwellers	United Kingdom
Unit:	Mood-modifying prescriptions	Prescriptions under NHS (47.2 million)
Eight leaders, making up over 50 percent		
1. Chlordiazepoxide (Librium)		Barbiturates 28%
2. Phenobarbital ^a		Other hypnotics 15%
3. Amobarbital (Amytal) ^b		Tranquillizers 36%
4. Secobarbital (Seconal) ^b		Stimulants and anorexients 7%
5. (Combination of 3 & 4) (Tuinal) ^b		Antidepressants 14%
6. Diazepam (Valium)		
7. Trifluoperazine (Stelazine)		
8. Butobarbital (Butisol) ^b		
a. Long-acting		
b. Short-to-intermediate acting		
(Classification in a and b based on Reference 5c.)		

U.S. Census

Period:	1971		
Unit:	Manufacturers' shipments for domestic use, U.S., ethical		
	Central Nervous System Drugs††	Millions of Dollars	Percent
	Barbiturates	\$ 26	5
	Other sedatives and hypnotics	27	5
	Tranquillizers	473	72
	Stimulants	70	10
	Antidepressants	56	8

* Cooperstock, R. and Sims, M., "Mood-modifying Drugs Prescribed in a Canadian City: Hidden Problems." *American Journal of Public Health*, 61: 1007-1016, 1971.

† Parish, P.A., "The Prescribing of Psychotropic Drugs in General Practice." *Journal of the Royal College of General Practice*, 21: 1-77, Supplement No. 4, 1971.

†† See Table II.

TABLE II

MANUFACTURERS' SHIPMENTS OF CENTRAL NERVOUS SYSTEM
DRUGS, UNITED STATES, 1971

Drug Class	Value of Shipments (Millions of dollars)		
	Total including exports	Ethical	Domestic Proprietary
All Pharmaceuticals	\$5,685	\$4,115	\$1,428
Acting on CNS and sense organs	1,527	1,118	396
Skeletal muscle relaxants	28	28	x
Internal analgesics and antipyretics:			
Narcotic	66	66	x
Nonnarcotic	575	245	324
Salicylates	90	6	84
Aspirin combinations	212	D	177
Anti-arthritis (non-hormonal)	88	D	D
Other	186	123	D
Hypotensives:			
Rauwolfia-diuretic	64		
" alone	11		
Psychotherapeutic agents:			
Antidepressants	56	D	x
Tranquillizers:			
Phenothiazine derivatives	119	118	x
Other	355	355	x
CNS stimulants:			
Amphetamines	44	43	x
Other anorexients	28	26	x
Other	1	1	D
Sedatives and hypnotics:			
Ethical:			
Barbiturates	26	26	x
Nonbarbiturates	28	27	x
Proprietary ^a :			
Sleep-inducers	18	x	D
Calming agents	4	x	D

x Not applicable.

D Omitted to avoid disclosure of individual firms.

a Apparently these are minor tranquilizers.

Source: Current Industrial Reports, Pharmaceutical Preparations, Except Biologicals 1971, U.S. Bureau of Census Series MA-28G (71)-1, Nov. 1972.

Volume of Production

According to the Congressional Research Service of the Library of Congress, there is no international reporting on production of the non-narcotic central nervous system drugs, although for the narcotic drugs, records are kept by the International Narcotics Control Board of the United Nations. The Convention on Psychotropic Substances, signed at Vienna, February 21, 1971, which is not yet in force, and ratification of which has not yet been approved by the United States Senate, provides for international reporting on psychoactive drugs (9). Article 16 states that each Party shall furnish standard annual statistical reports on manufacturers, exports, imports, and stocks held by manufacturers for Schedule I and II drugs, and similar information, except for stocks, for Schedule III and IV drugs. Amphetamines fall into Schedule II, barbiturates, meprobamate and methaqualone into Schedules III and IV. Quantities of preparations manufactured will not have to be included in the reports. Additional substances can be added to these schedules (Article 2) (10) on recommendation from the World Health Organization, if they are considered to induce dependence and central nervous system changes, and present any likelihood of abuse.

In the United States, drugs acting on the central nervous system and sense organs made up 26.9 per cent of the total manufacturers' shipments of "pharmaceutical preparations except biologicals" in 1971 (11). The figure for all pharmaceuticals was \$5,685,000,000, of which virtually all (97.5%) was intended for the domestic market. About three quarters of the total shipments consisted of "ethical" drugs, the term used for those ordered by prescription. Similarly, within the total for all central nervous system drugs the share of ethical products was about three quarters (73.8%). (See Table II).

The tranquillizer group made up a total of \$473,000,000 in manufacturers' domestic shipments. Sedatives and hypnotics accounted for \$53,000,000, slightly over half of this being for nonbarbiturates, and antidepressants had a sale value at the manufacturers' level of \$56,000,000. These three classes of shipments were headed almost exclusively for the prescription drug market.

Proprietary drugs, usually referred to as over-the-counter drugs, were important chiefly in the salicylate and aspirin combinations within the non-narcotic group of analgesics.

Figures cited by Dr. Parish for the United Kingdom, although not exactly comparable, show far less use of tranquillizers and more use of sedatives and hypnotics and of antidepressants (12,p.1). (These are figures for proportions of total prescriptions, not rates per person).

THE ASSIGNED TASK OF THE PHYSICIAN

In the United States the rise of psychotropic drug use in medical practice can be interpreted as an impairment of the expected role of the physician.

Society has delegated to the medical care system, and specifically to the physician, the task of distinguishing certain forms of incapacity, including states of feeling or mood to be labeled illness, from other forms. Such other forms can be dealt with by other professions (law) or social systems (criminal justice, schools), or by the individual and his/her immediate associates.

In order to discharge this function without hurting employment customs and other social rules, and without seriously impairing the individual's future or present income, the physician is theoretically trained to responsible performance by a socialization system. Also, various sanctions and supports are supposed to operate during the doctor's professional career, to keep him performing responsibly.

A mode of bringing about a doctor-patient contact is understood and used. The physician stands ready to respond when the patient initiates an encounter by an announcement of symptoms. For our purposes, a preventive visit not specifically responding to some public health campaign can be included in this model if the "symptom" is viewed as need for reassurance about wellness. Other initiation signals are respected: at recognized nodal points in life such as marriage, pregnancy, birth, employment change, and travel; or the launching of a new doctor-patient relationship upon joining an organized health care program, moving, and death or retirement of the patient's former doctor. Possibly these signals are less likely to lead to medication, unless they occur in combination with, and as reinforcement of, the symptom stimulus to see a doctor.

The capacity of the physician to carry out his task (distinguishing or diagnosing "illness") has been damaged, and in some cases even shattered, by the economic drive of the vendors of psychotropic drugs. This drive has been able to invade the doctor's decision area because of the receptivity of the patient which converts the prescribing act into market demand. The receptivity is based on the large range of conditions of contemporary life that generate stress, the emotional effects of physical disorders for which patients consult doctors, and the diffusion of information about availability. The patient is not reluctant to use a prescribed drug because social institutions have legitimized drugs. They are identified with technology and thus with progress, affluence and comfort. Ordered by a theoretically detached "other", they are sanctioned in a sense that is not true of alcohol, for example.

Tranquillizers and Stimulants

As far as the patient is concerned, the doctor has historically been acted upon to prepare him for this prescribing response. From testimony before the Kefauver committee on the early days of tranquillizers, it appears that, to secure acceptance of the new product (chlorpromazine), it was necessary to break the hold of the old technology for the limited treatment of mental illness (psychoanalysis and psychoanalytical psychotherapy) among psychiatrists. According to Dr. Lehmann, doctors had to be convinced that the newer drugs sedated without impairing reasoning power (13a). Smith, Kline and French, licensee for Rhône-Poulenc's chlorpromazine, is reported to have been one of the first drug companies to use detail men. From then on, an important part of the new technology lay in marketing method.

Tranquillizers — As the drugs converted custodial populations into patient groups, rendering in-hospital treatment programs operative, large-scale discharges moved the market for the tranquillizer drugs out into the community. To continue the market, tranquillizers had to be accepted as maintenance drugs. The next step apparently was to treat anxiety in order to prevent worsening of emotional problems leading to hospitalization. Instead of being confined to the post-discharge patient, the use of the drugs was urged on doctors in office practice to treat anxiety. Promotion of Miltown for pre-menstrual tension (1957) was an example (13b).

By 1960 the bulk of the advertising was for the minor tranquillizers aimed at anxiety states rather than hospital-type mental disease. Indeed, psychotropic drugs became the prototype of drug promotion through detailing and medical advertising, as well as through extension of the range of situations for which the drug was recommended to physicians (13c).

Stimulants — Stimulant drugs were part of this new drug explosion.

Amphetamines and anorexients make up a sizeable market within the class of central nervous system drugs, although academic medical judgment in the United States today accepts amphetamines only for two rare conditions — narcolepsy and hyperkinesia. Manufacturers in the 1960s claimed efficacy for at least eleven medical uses, and the drugs gained their ascendancy as antifatigue agents, remedies for depressive complaints, and aids to weight reduction. Mood-modifying properties that would assist the dieter to hold fast were claimed as assets. One can find top medical officials of government giving cautious approval to amphetamines for obesity and for combatting fatigue only a few years ago. However, so far as use for obesity is concerned, authorities withhold approval because the observed development of tolerance restricts amphetamines to short-term use; on discontinuance, since no control of appetite has been introduced, previous weight loss is regained (14). These discouraging findings were pointed out by Walter Modell in 1960 but industry claims, physician receptivity, and patient compliance continued.

The Physician's Vulnerability

The poor resistance of the practising physician to marketing pressures for mood-modifiers over a period of two decades can be partially ascribed to his having lacked continuing guidance that would improve his prescribing. There has been no effective method to update his perception of his responsibility and his range of choices. He has had no report of his own prescribing profile, or of the total drug intake of patients under care of more than one doctor, to guide his perception.³ His "trained incapacity" is perpetuated by contact with peers who are exposed to the same environment. Even in group practice his conditioned prescribing is not necessarily faced with challenge; in prepayment plans where the cost of drugs is covered there is rarely any effective utilization review, and the review process, where it does exist, is likely to consider only gross excess of numbers of drugs, not the fitting of the drug to the conditions. In fact, traditionally, it has not even been possible statistically to associate the drug record with the patient diagnosis and treatment record, because the investment in data gathering has not been made. (The development of the necessary record links is proceeding, but usually only for the indigent or elderly patient under public sponsorship (15).)

As the physician has typically been trained to register a clinical perception abstracted from other ways of looking at a patient, he is inadequately prepared to use resources outside the clinical framework of medicine to help the patient. Social services, nonmedical therapists, political activism, housing innovations and other remedies may be unknown, ignored, or undervalued in daily practice. Given pressures on the doctor's time, the psychotropic drug, advertised in his professional journals, often solves the problem of what to do. It is unlikely that he will invest the time to collect and ponder countervailing or ambiguous evidence from a variety of specialty journals.

³ Donald Rucker has noted these gaps in the statistical feedback to doctors. *Basic Methods for Optimizing the Rational Prescribing of Psychoactive Drugs, J. of Drug Issues* 1: 326-332, 1971.

OLIGOPOLY AND NEW DRUG PRODUCTS

The supply of psychotropic drugs originates in an oligopolistic industry of international scope. In the industry there are market leaders accounting for a large share of the aggregate production, and within each therapeutic class market, leadership is also pronounced. In the United States the dominant firms are surrounded by a much larger group of small firms with very limited market influence.

The drug industry is considered to be a branch of the chemical industry. This in modern form was founded on the development of new products from the industrial matrix materials of coal and oil. Joint production of several chemicals was characteristic of the industrial processes involved.

The major drug manufacturers follow the chemical industry pattern in that they are multiproduct firms with joint costs in many areas of production, research, and distribution. However, a single product may be dominant in the sales volume of a given firm. The rest of its line warns competitors that it's ready to fight back if its share of the market is threatened.

Some of the companies, by various mergers and acquisitions, have evolved into conglomerates with interests in a line of reagents and scientific instruments and also in a variety of other products. This diversification affords some protection against any sweeping change affecting the pharmaceutical industry as a whole. International links take the form of (1) sales of a single firm's products in countries other than the firm's home country, directly or through subsidiaries established abroad, (2) patent licensing agreements between firms of different countries, and (3) joint subsidiaries of two companies from different countries in a designated country. International flow of products is incomplete in that some drugs originating in one country are not offered for sale in other major markets where therapeutic alternatives exist, or where makers of these drugs do not seek or obtain marketing approval from the government of the importing country. However, international operations can be very extensive. Smith, Kline and French is reported in Moody's Manual to have over 20 subsidiaries in various parts of the world, and Pfizer is said to have 60 plants in 34 foreign countries, sales offices in 60 countries, and sales in over 100 countries.

The modern drug industry has been characterized by its search for new products and its tendency towards "nonprice competition." This is often found where overhead costs make up a large part of total product cost so that the short-run potential for price cuts is enormous. This tendency exists in particular where the market is limited (as, for drugs, by the biological possibilities of incidence of a given disease), thus restricting the potential for expanding sales of all manufacturers of a product through price reduction. Under these circumstances, rivalry between firms took the form of innovation. Products quickly became obsolete, and the ranking of firms within a product market changed as this occurred. Process patents were not effective and, with short market life, could not do much for the firm. But product research and patents were significant, two thirds of the prescribed drug market being for drugs under patent (16). Maintenance of a firm's share of the market appears to be the goal of research and of introduction of new products. Advertising is used heavily. Comanor found the size of the advertising budget to be correlated with the rate of return on stockholders' equity (17a).

Retail pharmacists could not compete in production owing to the technical superiority of factory production and patent control. The larger producers gained more than the

smaller ones from introduction of new products — evidently because they were better able to sell and distribute their stock (16).

The profitability of these manufacturing and selling activities in the early days of psychotropic drugs was notable. American Home Products Company, manufacturer of two tranquillizers, held the number one position among U.S. major industrial corporations in 1958 in terms of net profit as a per cent of invested capital. The second position was held by Smith, Kline and French, which priced its tranquillizer above the level of its other prescription products (13d).

The firms justified their wealth and revenue by appealing to what would now be called an image; the American pharmaceutical company was said to be reaping rewards of its creativity, motivated by scientific purposes and adhering to scientific standards.⁴

Claims of past creativity were somewhat impaired by borrowing and adapting the innovations made by others, by the luck of accidental discoveries, and by the trivial variations on a molecular theme emerging from drug firm laboratories. Nevertheless, the achievement of the major tranquillizers and antidepressants in working a revolution in the care of mental patients all over the world was acknowledged (13e). It should be recalled, however, that penicillin (preventing syphilitic paresis) and anticonvulsants (preventing psychiatric complications of epilepsy) contributed to this revolution and that government, rather than private industry, is credited with furthering the development of penicillin.

In recent years, charges by the industry that stricter Food and Drug Administration (FDA) controls slowed down development of new drugs call attention to the question of identifying important innovation.

Objective evaluation of therapeutic significance requires selection of appropriate variables for measuring clinical improvement, selection of critical values for rating improvement as significant, and weighing benefits against side effects. Therefore the extent to which any drug or group of drugs contributes to drug dependency and to impairment of the useful functions of physicians would have to be considered in measuring innovation. Furthermore, even if gains to the mentally ill attributable to drug therapy exceeded the negative effects, revenues from sale of mood-modifying drugs would not be exempt from concern unless there was no way of achieving the wanted effects without incurring the unwanted ones.

It appears that clinical pharmacology has big tasks ahead in achieving satisfactory evaluation. Use of market behavior (demand of consumers) as a test of innovation is compromised by irrational prescribing and irrational drug-taking.

What about claims of scientific identification? Although supported by an extensive laboratory technology, the credibility of the drug industry is lessened by its readiness to market fixed combinations; the use of research for obvious copying of rivals; promotion based on prescribing for symptoms; the creation of ill-defined syndromes; and the de-emphasis of side effects.

Because of the obvious relation to profit motives, price discrimination in international markets is upsetting to claims of scientific identification. Study of the contemporary international market shows that United States prices for drugs are high in comparison with prices in eight other countries, and this is consistently true for eight tranquillizers within a group of twenty leading drugs studied (18). Overall, the evidence is mixed.

⁴It was also said to be recovering expense of rigorous controls of manufacturing quality, and acquiring means for future research.

THE ROLE OF THE AMERICAN MEDICAL ASSOCIATION IN THE 1950s

The contents of the drug sales list have changed since the 1930s,⁵ but industry marketing practices have remained fairly stable since the wave of innovations and the rise or expansion of certain firms following World War II. In its initial market drive, the industry tried to bypass the American Medical Association Seal of Acceptance and to utilize means other than the Association's *Journal* to reach doctors. The AMA was concerned about the loss of advertising, and after commissioning study of the process of adoption of new drugs in a Wisconsin community, committed itself to a sort of partnership with the drug industry in which the pages of its journal would be receptive to drug promotion without independent AMA evaluation of drug safety or efficacy. The revenue would support AMA activities. In appearances before Congressional committees, spokesmen for major drug firms repeatedly interpreted criticism of their promotional efforts as implying distrust of physicians' ability to care for their patients. The AMA returned the service by protesting against efforts to investigate or criticize the industry (14, 19). It later revived its evaluation of new drugs and went so far as to publish in 1971 a reference book for doctors entitled *Drug Evaluation*, which was frankly critical of a number of commonly used products, including some heavily advertised in the JAMA.⁶ In planning a subsequent edition, the AMA removed responsibility for the contents from the Council on Drugs, an act interpreted by some as a weakening of its courage to be critical.

Besides revenue interests, also involved in the AMA's abdication may have been its relation to general practitioners in a period of emergence of specialties.

Rosemary Stevens, describing the trend of the postwar era (20), notes that specialty certifying boards were established, each predicated on

a goal of technological excellence in a defined specialty area, rather than as one component of a manpower plan for adequate service. As the specialty groups came to dominate graduate medical education (and thus the stratification of the medical profession) in the decades following World War II, a curiously structured profession developed. Medicine became a variety of disciplines exercised by specialists of exceptional competence. . . [Yet they] were practicing in the old isolation of solo or small partnership private practice. . .

Between 1942 and 1952 the total number of active diplomates of the medical specialty boards increased from less than 20,000 to more than 48,000 and by 1969 there were 131,517. By 1950, at least 50 percent of all full-time specialists were board certified, either by examination or through the boards' generous grandfather clauses; the proportion is little different today.

The rise of fragmented specialties set up a situation where some side effects and interactions among drugs were lost from view, a situation favorable to multiple and irrational prescribing. At the same time, the general practitioner, on the defensive professionally and economically, may have wanted and needed to assert his therapeutic power in dealing with patients. Perhaps students of internal politics of the AMA will assess how

⁵For example, the rauwolfia alkaloids, whose usefulness in treatment of psychotic behavior was given "highly sanguine" reports in the 1950s, were in later years much less frequently used and by the mid-sixties were considered far inferior to the phenothiazines. (3b)

⁶A study by the Library of Congress records the drugs both most frequently and most heavily advertised (number of pages) in the JAMA 1968-71. Forty drugs (two of them being different sources of nitrofurantoin) were listed (17c).

All but three of these were evaluated in the AMA's 1971 book; of these 37 drugs, three were rated as irrational mixtures (Librax, Donnatal, and Pathibamate). A fourth, Triavil, was criticized for overly broad claims which might lead to irrational use. Five others were questioned for other reasons.

these conditions of practice influenced AMA policy towards drug advertising and drug evaluation.

ELEMENTS OF DRUG POLICY

Several important types of policy decisions affecting medical use of psychotropic drugs concern the areas of (1) access to the market, (2) international evaluation of efficacy and safety, (3) therapeutic claims and disclosure of side effects, and (4) strengthening the capacity of the medical care system to offer alternatives.

The Case of Amphetamines

By way of introducing some of the policy issues, a brief look at amphetamines, discussed earlier, may be helpful.

Originating in a discovery by a Japanese scientist in 1919, amphetamines got their commercial start in the 1930s when Smith, Kline and French Laboratories marketed the Benzedrine inhaler (21a), which they later withdrew. Other similar substances and compounds were evolved. In 1970 the United States had four bulk producers of amphetamines and methamphetamines (21b). It is reported that 8 per cent of all prescriptions written in the United States around 1970 were for amphetamines. Pharmaceutical firms could buy bulk amphetamine from the producers for fabrication into dosage forms.

Restriction of these stimulant drugs to conservative indications would wipe out 90 per cent or more of the market in recent years — a reduction of close to \$40,000,000 by 1971 figures. Because of the direct interest of drug abusers in amphetamines, Federal authorities imposed controls on production and issued an order removing all injectable amphetamines and combination amphetamines for oral use (but not oral forms of amphetamine alone) from the market. Under such pressures, illicit and “gray” medical users turned to drugs with similar effects (22).

Such substitution is a problem when production control is the chief mode of attacking drug abuse. Although announcement and imposition of controls have a deterrent effect on some practitioners and some members of the public, supplementary approaches are needed if a change is to be made in the place of mood-modifiers in the medical care system.

The City of New York has petitioned the Food and Drug Administration to remove treatment of obesity from the list of approved indications for amphetamines and their congeners, and it is attempting to amend the Health Code to prevent “diet doctors” from dispensing amphetamines. The need for alternative information sources and assistance to the public in managing obesity problems has been recognized. But the New York City medical societies were not responsive to requests of the Mayor’s special committee to get their members to refrain from prescribing amphetamines for obesity.

Access to the Market

Psychotropic drugs have shared in the criticism applied to the pre-1962 process of drug approval.⁷ Today the United States is one of the few nations in the world which requires

⁷Specifically, in relation to therapeutic claims, full disclosure of side effects, and acceptability of clinical tests.

substantial evidence of a drug's effectiveness before marketing (by the Kefauver-Harris Amendments of 1962) (17b).

The problem of overuse of psychotropic drugs would not disappear if no new drugs were added to the annual stream of sales. However, some observers would welcome reduction of the number of new drugs. Despite the hundreds of drugs in existence, studies and market sales figures show a concentration on a few drugs in each therapeutic class. The burden of even remembering and considering many contenders simply becomes too great.

Access to the market unremittingly involves evaluation and re-evaluation of benefits in comparison with risks. Some favor granting market privileges to a drug that is "possibly effective" for certain patients who perhaps can't tolerate other rival drugs known to be effective. It has been argued that the benefit-risk comparison is best left to the prescribing doctor — a position supported by the industry. Nevertheless, peer judgment and expert-panel judgment concerning which drugs merit being placed in this category have considerable precedent and are consistent with the spirit of review of medical performance enacted in the Professional Standards Review Organizations and now developing in psychiatry in the United States. It is no novelty to have certain drugs labeled by hospital committees and other professional bodies as reserved for the occasions when the more common remedy should not be used or fails to perform. Today the according of approval to psychotropic drugs is inevitably affected by the necessity of appreciating the "side effects" of diversion to the drug abuse market and of conditioning large groups in the population to frequent recourse to drugs. In particular, a low addictive potential may induct the community into a generalized habituation. The demonstrated benefit must be large enough to make these risks worthwhile. We have not evolved a quantitative measure for the social costs involved, nor can we ascribe them to the specific drug that may be in question. This is a task in which the economist, sociologist and statistician can assist the policy-maker and administrator.

It has been pointed out that power to withdraw drugs from the market is as important as the power to permit their initial sale, if not more so. One reason is the length of time required to make a full assessment of side effects. Also, early appraisals of efficacy of a new drug may be biased by enthusiasm. Finally, experimental methods and scientific disciplines continue to evolve, and reappraisal may yield different results. Power to require withdrawal should be included in the concept of market access policy.

Might it not be desirable to establish differential criteria for access so that a high benefit/risk ratio would be required in a therapeutic class that has a plethora of drugs and is used for diseases of modest severity?⁸ In such a scheme, a lower ratio would be acceptable within a therapeutic class less well supplied with effective drugs and used for diseases of greater severity.

International Evaluation

The research technology of drug evaluation has developed greatly over recent decades as a result of trends in the basic sciences, the resources of clinical medicine, and refinement of statistical approaches. It forms a substantial part of the overhead in preparing a drug for marketing. Hence cost presents one reason that supports the case for formal international

⁸Criteria being morbidity or disability, mortality, and effects on the human fetus.

government collaboration. Another attractive reason is the possibility of accumulating adequate numbers of cases for statistically significant evidence on effectiveness and safety in a shorter time. Those who could benefit would thus have earlier access to a new drug.⁹ Some individual firms have partially internationalized the research process, but to reap the obvious economies involved and to protect the public interest, an official collaborative effort is needed. So far as psychotropic drugs, especially, are concerned, official cooperation may offer more possibilities for proper cognizance of the drug abuse problem.

Claims and Side Effects

Reducing the scope of manufacturers' claims for their products and increasing the amount of display given to side effects should logically make physicians more reserved in the support they give through their use of the prescription pad to the marketing plans of the manufacturers. This effect can be sought through governmental regulation of drug advertising.¹⁰ But we know from experience that doctors may fail to notice package inserts containing warnings; drug sales personnel seek fresh synonyms for the disallowed promise of benefit; and the reader confronted with a long list of drugs may overlook some significant danger. If consumers, and doctors as "natural attorneys" of the patient, had a more powerful voice, erosion of the intent of regulatory laws could be prevented. Certain doctors have taken up this role over the years of Congressional hearings on drugs. Consumers, with some help in developing their sophistication, could do more on their own. This could be one aspect of the work of consumer advisory bodies within a national health care system.

OFFERING ALTERNATIVES

Parish has pointed out how physicians with patients who are "doctor-dependent" are able to make them "drug-dependent" by repeated prescriptions, often arranged through auxiliary personnel (12,p.72). He also traces use of psychotropic drugs to the confusion within medicine about indications for referral of patients by a general practitioner to a specialist, and to factors influencing the rate of referral.

This finding is provocative because it brings out the issue of alternatives to drug-taking. Doctors have evidently learned the lesson of substituting auxiliary personnel time for their own, but are less effective in doing this without involving a drug regimen. It is often alleged that a doctor is reluctant to refer to a second doctor for fear of losing his patient. A referral pattern that is both economically and scientifically up-to-date and applicable to capitation reimbursement must be imparted to physicians. Alternatives to drugs to assist in stress can be made more readily available through community planning and financing of services, including both mental health services for "life point" stress and social services to strengthen the bereaved, divorced, disabled, and elderly. The financial

⁹Where length of time is essential in picking up side effects, other ways of protecting the public must be applied.

¹⁰In 1971 Dr. Henry Simmons indicated that Sandoz Pharmaceuticals had been obliged by the FDA to withdraw an advertising campaign for Serenitil (mesoridazine) in which the drug had been recommended "for the anxiety that comes from not fitting in" because the agency held that "this drug, a phenothiazine, is inappropriate for use for the problem of everyday living." The company had previously been requested to stop advertising the product as a treatment for alcoholism (6b).

and organizational resources of health insurance systems can be utilized to provide or refer to such activities, which can supplement other measures directly aimed at raising prescribing standards. The effectiveness of such alternatives in improving prescribing choices should be evaluated and not taken for granted. The many improvements in physicians' understanding of clinical pharmacology and drug evaluation that can be brought about by updating both undergraduate and postgraduate medical education and that have been cited by many expert observers and educators will not be reviewed in detail here; but they should clearly simplify the task of moving practitioners toward a more tolerable level of psychotropic drug use.

APPENDIX

Historical Note

Below are described certain portions of the extensive documentary record of public hearings on the drug industry that are of particular interest in relation to medical use of psychotropic drugs.

In 1959 and 1960 the U.S. Senate Committee on the Judiciary, Subcommittee on Antitrust and Monopoly, held hearings on "Administered Prices in the Drug Industry." Part 16 on Tranquillizers (1960), brought out issues on pricing, source of innovation, patents and licensing, therapeutic claims and side effects, and profitability. The early tranquillizers available in 1960 included chlorpromazine (Thorazine) and prochlorperazine (Compazine), both produced by Smith, Kline and French, meprobamate, produced by Carter as Miltown and by Wyeth (American Home Products, Inc.) as Equanil under license from Carter. Phenergan (made by American Home products under license from the French firm Rhône-Poulenc) and Stelazine (trifluoperazine) were also in the market, as well as promazine (Sparine) introduced in 1957 by American Home Products. Ciba's reserpine (Serpasil) was used as an antidepressant. Executives of Carter, American Home Products and Ciba were heard. Part 17 is the appendix to Part 16 and contains numerous documents on medical aspects of these tranquillizers, patent license negotiations, price trends, etc.

The same committee held hearings in 1961 on S. 1552 "Drug Industry Antitrust Act." Part 2 contains copies of some notable documents — the Fond du Lac study commissioned by the AMA on drug advertising, Modell's report to the AMA Council on Drugs, entitled "Status and Prospects of Drugs for Overeating," the Coleman and Menzel studies on diffusion of an innovation in drugs, Charles D. May's article on "Selling Drugs by 'Educating' Physicians," etc. Part 7 contains a *New Yorker* article (1962) on "Getting There First With Tranquillity—Onward and Upward With the Arts", which described the public relations efforts used to promote the tranquillizers.

In May 1962 the Antitrust Subcommittee of the Committee on the Judiciary of the House of Representatives held hearings on the companion bill to S. 1552, H.R. 6245. A thick record of the hearings and exhibits contains diverse points of view on regulating the drug industry. There is a detailed presentation expressing the philosophy of the Pharmaceutical Manufacturers Association, and a reprinting of Dr. Taussig's article in *Scientific American* (1962) on the deformities caused by "a mild and supposedly safe sedative," thalidomide.

The Senate Committee on Government Operations held hearings in 1963 on inter-agency coordination in drug research and regulations. It was the subcommittee on reorganization and international organizations that conducted the hearings. Part 2 contains exhibits, including a compilation and statement by Senator Humphrey on benefits and hazards of psychopharmacologicals (pp. 653-64). Part 4 contains testimony by Dr. Fritz Freyhan on psychotropic drug advertising. By this time Librium (Roche) had become the

most widely prescribed tranquillizer for office management of anxiety symptoms, according to *Medical Letter*, whose appraisal is included, as well as its reports on meprobamate, which are unenthusiastic. Supplementary exhibits on psychopharmacologicals appear. A drug warning letter on tranlylcypromine (Parnate) appears. Testimony in 1958 by an AMA spokesman reluctant to criticize tranquillizers is reprinted in Part 6.

The subcommittee on Intergovernmental Relations of the Committee on Government Operations of the House of Representatives held hearings in 1964 on the efficiency of the Food and Drug Administration in assuring drug safety both before and after initial clearance for marketing. Dr. Hugh Hussey of the AMA testified (Part 1) on the warnings of its Council on Drugs (Subcommittee on Blood Dyscrasias) on chlorpromazine as one of several examples of the AMA drug information program. Benefits of phenothiazines to mental hospital patients and the SKF package insert for Thorazine, with warnings and precautions for use, were introduced into the record by Dr. William Apple of the American Pharmaceutical Association (pharmacists) in support of a doctrine of benefit-to-risk ratios as a guide to release of a new drug (essentially no control, because in his opinion if even a single patient would benefit, release was justified).

The Senate Select Committee on Small Business, Subcommittee on Monopoly, under the chairmanship of Senator Gaylord Nelson, has held continuing hearings over a period of years on Competitive Problems in the Drug Industry. Part 5 (1968) is largely devoted to an industry-commissioned analysis of drug industry profits as being justified by risk, but includes criticism of this analysis by certain economists and papers by William Comanor. In Part 10, the issue of the country of origin of mental drugs was raised by Dr. Frank Ayd, responding to criticism of the industry; in this connection, material from the Library of Congress and from the NIMH on (a) international origins of phenothiazines, rauwolfia compounds, meprobamate, and the benzodiazepam derivatives, and (b) the role of Federal scientists in clinical trials of major tranquillizers and antidepressants was introduced. Part 13, on Psychotropic Drugs, contains discussions of the various tranquillizers in use today, the attempt of vendors to broaden the indications for their use, the state of present clinical evidence on their effectiveness, and the capacity of doctors to deal with drug manufacturers' claims. Patterns of use in the population are also under consideration here. Testimony by Drs. Balter, Freyhan, Levine, Brill and others is included.

Part 23 contains testimony by economist Sam Peltzman on his model for measuring net economic benefits from new drugs and his conclusion that the country lost more by restricting new drug approvals than it gained. It also contains a statistical compilation of JAMA advertising for the 10 most often and the 10 most heavily advertised drugs in the period 1968-71.

The same committee held hearings in 1971 and 1972 on advertising of proprietary medicines. Part 2 (1971) is devoted to mood drugs (sedatives, tranquillizers, and stimulants) and Part 3 (1972) contains information on anti-obesity drugs. The atmosphere of this round of hearings reflects concern with the physician's contribution to the drug abuse scene because of the broad indications on which mood drugs were introduced into the environment of young people, and because these drugs were being directly suggested to them to deal with the stress of examinations, etc. The risk of abuse of the anorexiants is placed by Dr. Jean Mayer in the context of a sophisticated understanding of obesity.

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The Social Responsibility of the Physician in Prescribing Mind-Affecting Drugs

Samuel Wolfe¹

INTRODUCTION

In a beautiful talk to the New York Academy of Medicine given just 40 years ago, in October 1933, the eminent medical historian Henry Sigerist placed the physician's role into historical perspective:

At all times the physician's profession gives him powers. He knows poisons — chemical, physical, biological forces of high potency are given freely into his hands. Secrets are divulged. . . which also gives him power. . . A misuse of this power is a serious menace to society, and so at all times society endeavored to protect itself by establishing rules regulating the physician's behavior. . . (1)

Is the physician's power too great at present? Is our society being over-medicated? Is this a new phenomenon? Has medical education kept pace with the pharmaceutical explosion of recent decades? Does the way the doctor practises affect the way he prescribes? Do his prejudices cause him to prescribe mind-affecting drugs selectively, for certain groups in the population? What is the doctor's responsibility in prescribing drugs that affect the mind? How shall the proper exercise of this responsibility be assured? What are the roles of the doctor, the medical educator, the medical profession, the politician and the public, in order to protect the public interest?

In this presentation, through the perhaps narrow range of vision of a doctor, and not through the eyes of a theologian or of a philosopher, an attempt will be made to explore

¹Department of Community Medicine, Long Island Jewish-Hillside Medical Center, New Hyde Park, Long Island, New York, 11040.

these questions, and to state a normative position for the doctor in our complex society, which may protect both the interests of the society and of the individual patient.

Are We Over-Medicated?

There are those who argue that the 19th century was a drug user's paradise, and that current trends are simply on a continuum. There are abundant evidences that doctors were key actors in a drama that led to opium addiction among many thousands of persons, especially women (2). Surely, though, it is ludicrous to argue that if there were poor and unpoliced prescribing practices in the 19th century, such practices should be permitted in our own era.

Some persons, such as spokesmen for the pharmaceutical industry, argue that we are under-medicated:

...an undetermined number of people use medications excessively. . .but certainly greater number. . .ignore them because they don't get medical attention, can't afford it, refuse it, fail to get prescriptions filled, endure pain. . .or. . .equate drug use with personal failings. On balance, then, we are probably an under-medicated society. (3)

Others have argued with some persuasiveness that we are over-medicated, that our society is being psychiatrized, medicalized, dehumanized, internally polluted, and that this process at least in western society is being aided and abetted by a medical profession that operates as an institution of social control (4, 5, 6). Zola, in particular, expresses a concern that the doctor in our society is not only meeting technical and scientific objectives but is also increasingly doing what *he* or *she* thinks is "for our own good."

Well said. Well expressed concerns. Yet, among those of us who have earned our livelihood in busy medical practices, seeing a patient every 11 to 15 minutes on the average, who can deny that we have used psychotropic drugs as the easy way out — to close off interviews, to control our patient's or our own anxiety, to give pills when other supportive services were not readily at hand or when our practices were not organized so that we could call on services that were readily available? (7) Some of those who have written most critically about the behavior of doctors in over-prescribing have never faced the dilemmas of the busy doctor. After all, doctors don't enter a world they have made, but one that they have inherited. They are victims of the business world of the larger society, of which they quickly become a part. As we have noted elsewhere, as told to us by a busy doctor:

My wife and I never pay for our own medications. I have a deal with the detail man from the (_____) pharmaceutical company. He's a hell of a nice guy, and we occasionally go for a drink together. He supplies antibiotics. . .vitamins. . .birth control pills. . .Why the hell shouldn't I write prescriptions for my patients using his company's brand name? (7, p 64.)

Charlotte Muller has clearly spelled out the case for the overuse of medications by the medical profession in our society (8). Psychoactive drugs accounted for 28.3 per cent of domestic sales of drugs in the United States in 1969.

The studies by H. J. Parry and I. H. Cisin, as reported in *Licit and Illicit Drugs* show that psychoactive drugs had been used by 13 per cent of adult males and by 29 per cent

of women during the previous year. Six per cent of males and 12 per cent of females used these drugs for at least one month to 6 months or longer during the previous year. The legal sources predominate: in the U.S.A., 149,000,000 prescriptions for psychotropic drugs were written in 1964, 214,000,000 in 1970 (most of the increase accounted for by the use of anti-anxiety agents), 260,000,000 in 1972. Clearly, many of these drugs get into the so-called grey market, into informal channels whereby friends share their prescriptions with one another (2, Ch. 61, 62). A 1972 Ford Foundation report points out that in a recent year the U.S.A. produced 4 *billion* doses of barbiturates and 8 *billion* doses of amphetamines, half of which had probably been diverted to illegal channels (9)! As long ago as 1956, 1 *billion* doses of meprobamate were sold in the U.S.A., according to Dubos (10).

In his excellent study of prescribing practices by British general practitioners, Peter Parish has shown that the problem of inappropriate and probable over-prescribing of psychotropics in the National Health Service is a very major one (11). Thus, we see that in three capitalist countries, Canada with its national insurance for hospital and physician services, Britain with its national health service, the United States with neither national health insurance nor a health service, there seem to be grave problems in the overuse of prescribed psychotropic agents. I do not have comparable data for Eastern bloc countries, but it is my understanding that, for whatever reasons, psychotropics are not yet as generally available as in the countries noted above. While alcohol has been cited as an increasing problem in these countries, it is also a problem in the so-called "free" world, in either case alcohol is *not* prescribed but psychotropic medication is. One would expect that prescribing rates in general, and hence, also for psychotropics, would be higher in a system of care such as obtained in Britain, which pays most of the drug bill; yet the rates of prescribing of psychotropics seem to be higher in the U.S.A., in spite of the inadequacies of insurance to pay for ambulatory care in general and for pharmaceuticals in particular.

Clearly, the inappropriate use of all prescribed drugs is a substantial problem, and Donald Brodie, in an excellent report (12) on issues relating to drug use review and control, cites as evidence the 1.5 million annual hospital admissions in the U.S.A., as the result of adverse drug reactions. An equivalent figure in Canada would be 150,000 annual hospital admissions. As well, Brodie estimates that at least 25 per cent of prescribed drug therapy avails little or nothing in terms of patient benefit, and hence is really "drug waste."

The proportionate contribution of misused psychotropics to the "drug waste" issue must be very great indeed. We know from a great variety of sources that such drugs are used for organic diseases where they are not indicated, are used for the treatment of garden-variety unhappiness, frustration, and normal states of sadness. Many within the medical profession seem to have come to believe that anxiety is abnormal and must be prevented or controlled through the use of drugs. We also know that the numbers of cases of over-dosages of psychotropics that are seen daily in emergency rooms in the United States and Canada alone runs into the thousands; young children are admitted to hospitals daily, poisoned by the family drug cabinet psychotropics that were thought to be candy. While probably more children may be admitted as the result of aspirin poisoning, the aspirin in the home has not usually been prescribed by doctors.

It seems clear then, that while there may indeed be many persons *not* on psychotropic drugs who ought to be, there is substantial evidence that there is an inverse relation between the production of psychotropic drugs and the indications for their use.

Obviously then, as Muller has pointed out, if there are factors that contribute "to a less than ideal use of the power of pharmaceutical technology for human benefit," (8) these need to be identified and corrected.

EXAMPLES OF SELECTIVITY IN PRESCRIBING

1. *Women.* As with opiates in the 19th century, so with psychotropics in recent decades: women are 2 to 3 times more likely than men to have such prescriptions written. A recent paper by Lennane and Lennane suggests that certain female sex-linked problems where there are solid evidences for an organic basis (examples include dysmenorrhea, nausea of pregnancy, pain in labor, infantile behavior disorders) tend to be labelled as psychogenic in origin, and treated as such. The authors suggest this is a possible manifestation of sexual prejudice (13).

2. *Children.* There is a rapid and dangerous trend to the treatment of children with presumed behavior or learning problems with stimulant psychotropic drugs. As Sroufe and Stewart point out in a recent important paper, children so classified could, at the very least, total close to 8 per cent of the elementary school population, and the use of stimulant drugs should be carefully and critically appraised (14). There is some evidence that the long-term outlook of hyperactive children treated primarily with drugs is poor (15). That should not be meant to imply that the outlook with other modalities is necessarily more favourable.

Though the statistical basis for the inferences have been substantively disputed, there has been a suggestion that amphetamine products used in childhood may alter rate of sexual development as well as growth in general, through alterations in the release of growth hormones (16). There are ways to treat hyperactive children other than with the use of drugs. As well, studies of children on such drugs have shown that some are monitored poorly, or have been put on such drugs as the result of a telephone contact! Sroufe and Stewart conclude that, while there is a place for stimulant drugs in a small number of children with behavior and learning problems in the presence of major organic disease, there is an even greater place for caution and skepticism in the use of such drugs for the great majority of children with hyperactivity or specific learning or reading disabilities. As the authors point out, a drug treatment cannot teach a child anything. Nor is a more compliant child necessarily a better learner.

3. *Patients with mental disorder.* Bernstein and Lennard have made an impressive case for the tragic consequences of a short-sighted medical approach to human problems, in their focus on the policy implications relating to the thousands of persons with *tardive dyskinesia*, a neurological disorder with possibly irreversible effects which results from prolonged use of the phenothiazine family of drugs such as Stelazine, Thorazine (U.S.), Largactil (Canada and U.K.) (17).

As the authors ask, what combination of vested interests, forces, ideological blindness, and wishful thinking conspired to keep this problem out of our awareness and under wraps? Where was the leadership?

4. *Patients in institutions.* There is little doubt that great numbers of patients in mental hospitals, in nursing homes, in geriatric centres, in centres for retardates, and

many persons confined to prisons, are being treated in large measure with psychotropic drugs in order to make them more tranquil, more passive, more malleable, easier to manage. Drugs are being utilized as substitutes for therapeutic environments, for support personnel, for health teams, as substitutes for tender loving care, for warmth and compassion and human understanding.

5. *The poor and minority groups.* We know that middle and upper class patients, while heavy users of psychotropics, are also likely to be substantial users of psychotherapy, group therapy, encounter therapy and supportive therapy provided by a wide variety of sources. But the poor and especially the poor black, the inarticulate, the Puerto Rican and Chicano poor, who are heavy users of outpatient clinics and emergency rooms run by interns and residents who rarely if ever get to know their patients well over a period of time, often receive psychotropics as substitutes for the counselling they need, for the job opportunities and educational supports they ought to have. Some say that doctors who prescribe psychotropics to the poor are the slumlord's best friend. Admittedly, alcohol is used as an opiate by the poor. But it is *not* prescribed. There is also good reason to believe it is used as an opiate by the higher income groups. Psychotropics may help to keep those who are in poverty tranquil. In Viet Nam we defoliated the crops; back home we now have the capability to defoliate minds. We neutralize and render passive human angers and anxieties that are often appropriate.

THE WAY THE DOCTOR WORKS

For whatever reasons, doctors may be more vulnerable to the use of psychotropic drugs themselves, thereby leading to a greater likelihood that such agents will also be used for patients. The ingenious study by Vaillant and his colleagues showed that over a 20-year followup period, doctors when matched with controls, used alcohol and tobacco as did the controls, but were far more likely to use tranquillizers, sedatives and stimulants. Concerns have been expressed about the possible effects on future behavior towards patients, when doctors and/or medical students adopt permissive attitudes to such drug use for themselves (18).

While the evidence is not entirely clear, there seems to be some reason to believe that doctors who are more subject to peer review and pressure are more likely to be safe and cautious prescribers. Such caution seems to extend across all their prescribing practices, and not just in the way they prescribe psychotropic drugs. It follows then that a key element in the development of standards for prescribing is the development of a formulary (19). There is also every reason to believe that hospital prescribing will be more judicious in settings where (1) the clinicians reach a consensus on standards for therapy, and educate the staff regarding the standards; (2) the pharmacists are in regular active communication with the prescribing doctors; and (3) a formulary committee establishes drug lists, reasons for selection for the lists, indications for use, and standards for prescribing and for prescription refills (20).

Our own studies in a lay-sponsored community clinic or health centre in Saskatchewan suggested that the prescribing rates were very low (one prescription for every two office visits); psychotropics were prescribed on 141 of every 1,000 office visits. Peer review of the work done in office practice was part and parcel of this group practice's ongoing activity at the time of the study (7).

A large prepaid group practice in Seattle has shown markedly lower prescribing costs than national averages in the U.S.A., and part of this is due to control of the use of psychotropic drugs under their drug insurance benefit (21).

Several researchers have looked at psychotropic drug prescribing patterns in prepaid group practices, in Washington, D.C., and in New York. While the rates seem to be lower than reported national averages (for example, 12 per cent of all prescriptions in the New York Health Insurance Plan study were for psychotropics), nevertheless there were evidences that a lot of psychotropics were prescribed for non-psychiatric conditions, a great many of those who were given psychotropics had their prescriptions refilled 5 or more times during a year, and most such prescriptions were written by family physicians rather than by psychiatrists (22, 23, 24). Clearly, the evidences for the effects of organization of medical practice on prescribing of psychotropics in particular, are not yet in.

The Doctors' Dilemmas

The doctor is on the horns of a series of very serious dilemmas. These may be summarized as follows:

1. He is poorly trained in pharmacology and has a poor knowledge of the therapeutic effects of many of the drugs he prescribes. Thomas Maren has emphasized the crucial need for undergraduate, house staff and postgraduate training of doctors in pharmacology: "for the physician is in ultimate and perfect control; no ethical drug is bought or taken that he does not prescribe." (25)

Louis Lasagna has also stressed the need to improve continuing education for doctors in pharmaco therapeutics, as well as better education for the public and for legislators on this subject. He wonders whether new and formal mechanisms may be needed in order to monitor the competence of doctors in prescribing. He stresses the grey areas in which we are at present working. We don't have clear definitions of efficacy and toxicity of alternative drug prescriptions for given conditions; and we do not have good inventories of patient characteristics in relation to drug responses. The three perennial causes of trouble in regard to monitoring the quality of medicinal drugs — ignorance, ineptitude, and fraud are still operative today (26).

2. The doctor is often the willing victim or accomplice of the pharmaceutical industry's propaganda mills, as Lasagna has shown in his cryptic chapter on *The Drug Industry and Medicine Avenue* (27). After all, the doctor is charged with responsibility for the public welfare. But the interest of the pharmaceutical industry in our society is not the public welfare but the profit it returns to its stockholders. This is a sad but true fact. It is also sad but true that the key sources of knowledge about drugs for many doctors comes from the partial truths, the half truths and the untruths of the industry. As Lasagna points out, from a company whose earnings were skyrocketing, doctors received pillows and slippers to plug the "peace of mind" associated with a tranquillizer. The same company has run golf tournaments, given out golf balls, has paid green fees and provided free golf lessons. For nongolfing physicians the company provided fishing contests, bowling tournaments, skeet shoots. Three thousand acres were rented to entertain 700 duck shooting MDs! (27 pp. 135-136).

At the same time, we know that thousands of doctors sell the products they themselves prescribe in the field of drugs, and doctors are stockholders in local and regional pharmaceutical companies (28).

3. The doctor receives poor leadership relating to prescription-drug policies from the American Medical Association. There is no doubt that the AMA was a progressive force in this field in the first decade and a half of this century (29). But there is also no doubt that in the decades since, there was a gradual but relentless abandonment of principled ethical advertising in the AMA journals: in 1966 alone \$13,000,000 of AMA income came from advertising (30).

4. Even the doctors' best journals, such as the prestigious *New England Journal of Medicine*, are packed with pages of pharmaceutical advertising propaganda, much of it of doubtful merit, often overstated and grossly exaggerated in its claims. And yet there is little doubt that this journal could retain a huge readership if it eliminated advertising of pharmaceuticals, published definitive reports on drugs, and doubled or even tripled its subscription costs.

5. The doctors' present sources of information about drugs are so inadequate that much greater encouragement needs to be given to the dissemination of publications such as *The Medical Letter on Drugs and Therapeutics*.

6. The doctor may need more training in human values and in ethics. After all, probably 90 per cent of the drug prescriptions he can write today were unknown a couple of decades ago. Does he have a keen enough awareness of the ethical issues associated with the use of drugs that may change or modify the behavior of patients?

7. Is the doctor sufficiently sensitive to the fact that *informed consent* will increasingly require the physician to spell out the contents, and limitations, of proposed medications that are prescribed? And is the doctor equipped to handle the notion that he may have to start sharing things with patients, rather than doing things to them, or *telling* them what's good for them?

8. Can the doctor face up to the key dilemma, that in our society — even in the supposedly socialist British National Health Service — he works essentially, by and large, as a little private entrepreneur? He runs a village spinning wheel in his office, in an age of technology. More often than not he still works by himself or in a very loose partnership, without the group and team arrangements, the pooling and sharing of skills and knowledge at his immediate finger tips, which would enable him to break out of the mould of writing a prescription in order to terminate an interview or a consultation.

The Doctor's Responsibility

In spite of the formidable dilemmas that face the doctor, still and all, it is his pen that writes the prescriptions for the psychotropic drugs that affect the mind. It is the doctor's judgment on which the patient relies, when prescriptions are written. Clearly, constructive steps can be taken to modify the extent to which drugs in general, and psychotropics in particular, are prescribed. Charlotte Muller (8) and Peter Parish (11) have outlined such steps.

The following are suggested as the Ten Drug Commandments for the doctor who is exposed to the temptations of prescribing drugs that affect the mind:

THE TEN DRUG COMMANDMENTS

1. Thou shalt take a careful history and make decisions about what the problems are by getting to know thy patient, before prescribing such drugs.

2. Thou shalt prescribe such drugs based on thy clear understanding of their effects on this particular patient. Thus, thou shalt prescribe in modest amounts, subject to regular review.

3. Thou shalt encourage the development of disciplined formularies for use in hospitals, as well as in community practice, and thou shalt cooperate in procedures to review the use and quality of drug prescribing, both in thine own hospital and office practice, and also in the practices of thy sisters and brethren within thy profession.

4. Thou shalt refuse to accept free samples from drug houses, thou shalt return them to the sender, and thou shalt encourage the rejection of advertising by the journals of thy noble profession.

5. Since doctor means teacher, thou shalt play a part in the education of thine own patients and of the community at large, regarding the proper use and the abuse of medications.

6. Thou shalt not participate in any venture that benefits thee directly or indirectly, that relates to the sale or distribution of any drugs, or drug products.

7. Thou shalt view favorably participation in group or team practice of thy profession, so that thou mayest draw on the skills and help of others, so as not to lean too heavily on a desire to prescribe. If thou insistest on solo practice, then thou shalt familiarize thyself carefully with the health and welfare services and agencies in thy community that can help thy patients. Be not so stiff necked as to refuse to seek help for thy patients beyond the writing of prescriptions that may be of little long-term benefit.

8. Thou shalt be cognizant of the fact that the apothecary and later the pharmacist was not meant to be a seller of Kotex and jelly beans, but was meant to be a member of a health team, knowledgeable in pharmaceuticals and a potential natural educator of both thy profession and of the public.

9. Thou shalt take regular retraining with a focus on updating thy information about pharmacology and therapeutics, and thou shalt support measures to require re-licensing examinations for members of thy profession at regular intervals.

10. Thou shalt maintain a sensitive concern for human values and for ethical issues, which will guard thee against tampering with patients' minds and thoughts through the use of drugs, without a clear understanding on thy part, and also the clear agreement of thy patient.

And if you honor these Commandments, doctor, then you are really a doctor, which is what you were intended to be when the State delegated you so much power and authority under its professional licensing statutes.

CONCLUDING NOTE

There is no substitute for the socially responsible individual. If the Nazi holocaust, the killing of peasants in Southeast Asia, and indeed, the tawdry events of Watergate, have taught us anything, surely it is that men cannot escape their individual social responsibility. This applies with very great force to the physician.

As the physician-statesman René Dubos has written:

Fifty years ago, a physician, like an engineer, could approach his tasks with the confidence that he was acting as a benefactor of humanity. In contrast, medical technology is now so powerful and often so indiscriminate that it can damage human personality even as it improves the functions of the body. The most

cruel dilemma of modern medicine is to decide which aspects of man's nature can be ethically tampered with and which ones should be respected at all cost. There is no guide to resolve this dilemma, beyond Montaigne's admonition: "Science without conscience is but death of the soul." (31, p. 437).

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Prescribing and the Relationship Between Patients and Doctors

Ann Cartwright¹

Parsons (1) has described how the sick person's exemption from normal obligations is accepted on the condition that he attempts to get well again. In Western society the most acceptable ways to do this are to consult the doctor or take some self-prescribed medicine. If a doctor is consulted he may, in Dowling's words, "prescribe a drug because he is afraid of "not doing anything." Doctors are active men. . . They are restive under inaction; to them inaction smells of defeat." (2) As Freidson (3) puts it: "The aim of the practitioner is not knowledge but action. Successful action is preferred but action with very little chance for success is to be preferred over no action at all." The most frequent action doctors take is to prescribe medicine. So when people are ill society expects them to consult a doctor and the doctor's training prompts him to take some action – usually the prescription of a drug. This in turn generates an expectation among patients.

Osler, in 1904, maintained that "the doctor's visit is not thought to be complete without the prescription" (4) and Jefferys argued in 1973 that it is "clear from anthropological and historical studies that those who do not take some "mind-bending" chemical concoction regularly or on ritual occasions have been the exception rather than the rule in all known societies." (5)

It is against these propensities and the interests of the pharmaceutical industry that we need to view the actions of doctors in prescribing, and patients in taking, medicines.

Most studies of variations in prescribing habits have looked either at doctors or at patients rather than at the relationship between the two. Doctors' attitudes, training, age and circumstances in which they work have been examined by Benjamin and Ash (6), Lee, Draper and Weatherall (7), and Joyce *et al.* (8). Others have studied patients either as

¹Institute for Social Studies in Medical Care, 18 Victoria Park Square, Bethnal Green, London, England E2-9PF

individuals or collectively as members of a town or area with particular characteristics (9). Some researchers (for example Parish (10), Dunnell and Cartwright (11)) have used both methods of approach and a few, notably Balint *et al.* (12) have also considered the interaction between the two. This paper is concerned with the nature of the relationship between patients and doctors and the ways in which this may affect prescribing. It looks at the various stages in the process by which a person gets and takes a prescribed medicine and tries to show how the doctor-patient relationship may affect each stage — starting with the recognition of ill-health.

RECOGNITION OF ILL-HEALTH

Whether or not a person perceives himself as being sick varies with the expectations and norms of the society in which he lives. A person's perception of ill-health is also likely to be affected by his experience of what his doctor has accepted and responded to in the past. Symptoms a doctor has dismissed as normal or insignificant may become accepted as part of themselves or as an attribute of their age or sex and no longer seen or explained as being the result of ill-health.

There are various indications that people's expectations about health may be rising. The relationship between ill-health and sickness absence appears to have changed in Britain, and less serious illness is increasingly regarded as justification for absence from work (13). But people still regard certain symptoms as compatible with health. In a survey of 1,412 adults in 1969 (11) Karen Dunnell and I found that two-thirds of them described their health as excellent or good but at the same time those who did so reported an average of three symptoms in the two weeks before they were interviewed. Complaints reported relatively frequently by the healthy were headaches, trouble with skin, teeth, feet and minor accidents. These are fairly common conditions and, except for headaches, affect the person externally rather than internally and may therefore be seen as not basically threatening. Given the widespread prevalence of symptoms there is great scope for the nature of the patient-doctor relationship to influence the extent to which these symptoms are seen as deviations from normal health.

PATIENTS' CHOICE OF ACTION

Once a person sees himself as being ill or having some symptom of ill-health, what influences the action he takes about it? He may consult a doctor because society expects him to, but he is more likely to take a specific symptom or problem to the doctor if he thinks the doctor can cure or relieve it. We were able to demonstrate this in a retrospective study of the last year of people's lives (14).

We asked the relatives and friends we interviewed whether the person who died had any of the following symptoms in the last twelve months of his life: pain, sleeplessness, loss of bladder control, loss of bowel control, unpleasant smell, vomiting or feeling sick, loss of appetite, constipation, bedsores, mental confusion, trouble with breathing, or depression. If the deceased had had a symptom while he was at home we asked if anyone's advice had been sought about it and if so whether that person had been able to help in any way.

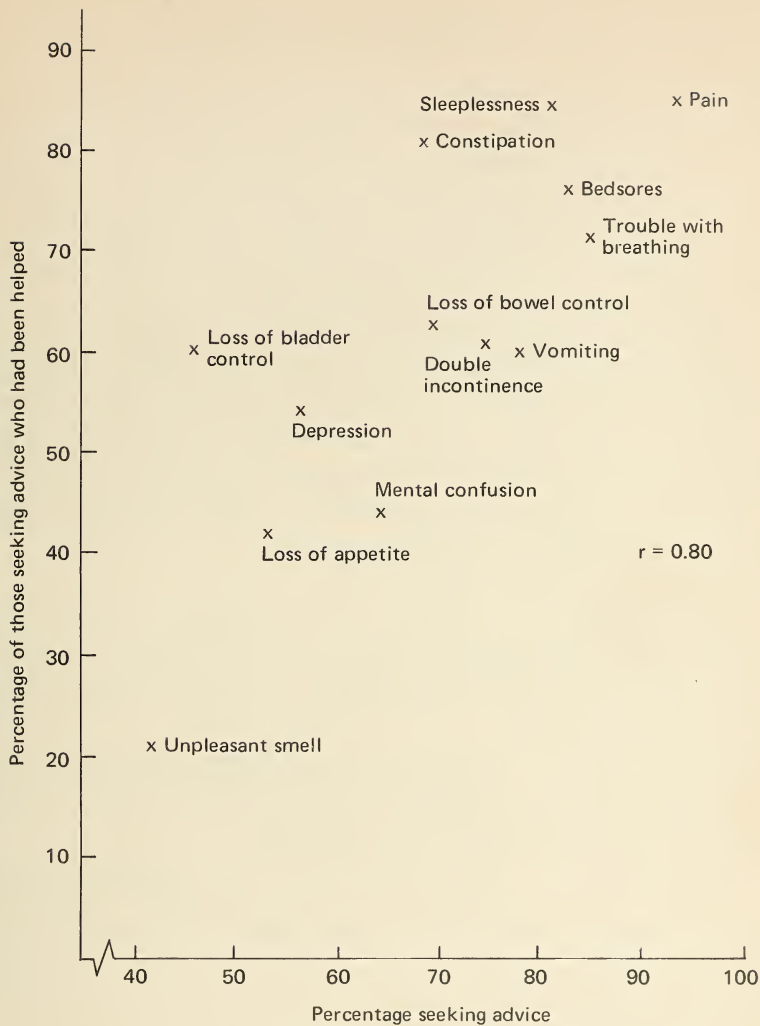


FIGURE 1 *Relationship between proportion consulting about different symptoms and proportion helped when they did consult*

The relationship between the proportion consulting and the proportion of those consulting who had been helped, is shown in Figure 1 for the different symptoms. One of the main reasons for people not seeking help for a particular symptom would seem to be a realistic assessment of the probable outcome.

Other data from the same study suggested that women may feel it more appropriate than men to seek support when they are bereaved and doctors may feel it easier to offer comfort in such circumstances to women than to men. We found a difference between men and women greater than that usually observed in consultation rates in the support they sought from general practitioners when they were bereaved.

Further indication of the influence of the patient-doctor relationship on the patient's decision about whether or not to consult a doctor comes from the variations in consultation rates between doctors. A study covering 171 doctors showed variations from 2.7 to 9.2 consultations per patient per year (15). These variations could not be explained by differences in the age, sex or location of the practice patients and may be due in part to different types of interaction between patients and doctors.

THE CHOICE OF ILLNESS

Individuals may or may not perceive themselves as sick when they have certain symptoms. They may, within certain limits determined by social pressures and the severity of the symptoms, consult or not consult a doctor. Their choice also extends to the way in which they present their perceived ill-health to the doctor. And it is in this area that the interaction between doctor and patient is probably most important. The choice of illness in many cases will depend on both doctors' and patients' perceptions of the symptoms and on their attitudes to and expectations of each other.

At this point I would like to digress and describe a study we are now doing at the Institute for Social Studies in Medical Care, which will, I hope, eventually throw some light on this process. We are looking at a series of consultations in general practice from different viewpoints: interviewing patients immediately before and after they see the doctors and again in their homes about ten days later, tape-recording the consultation, interviewing the doctor at the end of the session at which the study consultation occurs and extracting information from the medical records.

Points covered at the various interviews are:

1. *The patient beforehand.* His hopes, fears and expectations about the consultation in general and then specifically in relation to examination, referral, prescription, advice and other treatment. Points he would like to tell the doctor and other points he feels are relevant to his problems.

2. *The patient afterwards.* His account of the advice, information and treatment he was given. His perception of any problems he is likely to encounter in carrying these out. His satisfactions and frustrations with the consultation.

3. *The doctor afterwards.* His perception of what the patient wanted at the consultation. His account of the advice, information and treatment he gave. His impressions of what the patient understood and how far the patient accepted his advice. His impression of the patient's satisfactions and frustrations. His own satisfactions and frustrations. His views on his relationship with that patient.

4. *Follow-up to patient.* Outcome. How far advice carried out. Difficulties encountered. Other advice given and sought. Other prescribed medicines taken. Information about home and family. How much he thinks the doctor knows about him, his home, family, work, past and present illnesses. His views on his relationship with the doctor.

5. *The record.* Information accessible about patient's family, previous consultations, and the diagnosis and action record at the previous consultation. What recorded at study consultation.

So far we have studied about 50 consultations (five with 10 doctors who were known to be interested in this type of research). All these consultations have been with people aged 65 and over. We chose this group because we wanted to limit the study in some way and our interest in elderly people followed on from a number of our previous studies. In addition, elderly persons often have more than one thing wrong with them at a time so that the problems of selection, presentation and communication are more complex. I will be drawing on some material from this study to illustrate the points, but there are a number of drawbacks to these data which need to be appreciated. An obvious one is that the doctors were not selected at random. (We have since approached a random sample of 70 doctors and so far 11 (16%) have said they were 'prepared to consider' taking part in the study.) Next, both doctors and patients are likely to have been influenced by the study. (We hope to build in one or two methodological studies to look at

some aspects of this but we cannot hope to measure all the effects and they may be considerable.) In addition to selecting only patients aged 65 or over, they were chosen on the basis of *consultations*; as far as patients are concerned our "sample" is therefore biased towards those who consult the doctor relatively frequently. Finally, much of the material is derived from interviews and depends on the willingness of both patients and doctors to tell us their views and feelings about the consultation.

To return to the main theme: — patients may present their problems to the doctors in ways they feel are acceptable to him and in ways they feel will help their relationship. They are likely to emphasize the aspects of their ill-health to which they feel the doctor is most sympathetic and to stress the symptoms which they regard the doctor as most able to treat. Some may want to create or enhance an image of being a good, brave or independent patient. Some may want a continuing relationship with their doctor and so will be anxious to make it easy to come back.

A doctor in our present survey contrasted the way three of his patients seen at the study consultations presented their problems. One he felt was a 'success' because the reason for the consultation was openly recognized as being for marital problems and depression. Two others he felt did not have this insight. One had been told by the hospital she had asthma, although the doctor did not think this was an appropriate diagnosis. In his view she had shortness of breath brought on by anxiety or hysteria. A third woman also suffered from depression and a dry mouth. She reckoned the dry mouth was caused by the drugs she was taking for her depression. In the doctor's view the dry mouth preceded the treatment for depression and was 'a classical Jewish symptom of depression.' But he did not explain this to her as he felt it would be tantamount to calling her a liar. In the doctor's view these three consultations illustrated the way in which patients create their own diagnoses. They also show how doctor and patient may agree or disagree with an interpretation or how they collude.

In a study in 1964 (16) the proportion of adults who said they would consult their doctor about a constant feeling of depression was 54 per cent. The response to a similar question in 1969 showed that 72 per cent would do so (11). During this time the number of prescriptions for antidepressant drugs dispensed by chemists in England and Wales rose from 3.5 millions in 1965 to 6.4 millions in 1970. Patients are probably more likely nowadays to feel that depression is an appropriate illness to raise with the doctor because doctors themselves are more interested and concerned about it since they feel they have a more effective and straightforward way of dealing with it. What counts as an illness in the consulting room, and the diagnostic label attached to it there depends to some extent on the remedies available.

The form in which patients present their symptoms also depends on their anxieties about their condition. Here we found in our current study that they often presented their symptoms and fears rather differently to the doctor than to our non-medical interviewer with whom they had no continuing relationship.

One woman said to the study interviewer, before she saw the doctor, that she had come to see the doctor because of pains in her chest which she thought might be due to her heart or possibly to indigestion. At the consultation she described the pains in detail but only said they might be due to indigestion. She repeated this 'diagnosis' several times and said nothing about her feeling that the pains might be caused by heart trouble until the doctor eventually asked her directly if she thought this.

Another patient wanted to see the doctor "because I'm so big in the tummy." She said she had no particular worries, in reply to a direct question about this but later told

the study interviewer "my daughter had cancer of the stomach and you do think of these things." She did not verbalize this fear to the doctor but he examined her thoroughly and apparently reassured her. After the consultation she said: "He examined me inwardly as well. There's no cancer. That's all I was worrying about."

Korsch *et al.* (17), studying 800 patient visits to the walk-in clinic of the children's hospital in Los Angeles by tape-recording the consultation and interviewing the patients afterwards, found that only a quarter of the patients' main worries were specifically mentioned to the doctor by the patient during the medical visit.

Patients may hesitate to express their fears openly to the doctor because they are worried he may confirm their anxieties, or because they feel it is not appropriate for them to offer a 'diagnosis'. The 'illness' that the doctor responds to will therefore depend on his sensitivity to unmentioned anxieties. Again he is likely to be more sensitive to conditions he feels he can treat or cope with than about those he cannot.

We found too that the doctors in our study quite often felt they had 'treated' or 'checked on' a social or psychological problem which may have been the 'real reason' for the consultation, but that the patient did not mention this problem to us. Sometimes this may have been because the patient was unwilling to discuss a problem, such as a difficult marital relationship, with us. Sometimes the patient may not have recognised or faced up to the problem which the doctor had diagnosed — such as loneliness. In other cases a patient may not have realised that the doctor considered a problem relevant, such as an awkward father-in-law or poor housing. And sometimes the doctor appeared to be mistaken; for instance, one doctor thought a patient lived alone and suffered from social isolation, whereas he was living with his wife.

THE AMOUNT OF ILLNESS

The doctor-patient relationship may also influence the number of illnesses and problems discussed at a consultation. Several studies have shown that doctors are often unaware of the disabilities of their elderly patients (18).

When a doctor is consulted about one condition he does not necessarily ask or find out about other problems (19). As one patient on our current study said when we were asking about other illnesses or problems: "Don't send me in with too many complaints. He's got too many patients to see already. He'll think I'm a hypochondriac." The likelihood of the doctor finding out about other problems may depend in part on his willingness to spend more time on a particular consultation. This was demonstrated by Silver (20). The chance of uncovering additional illnesses and conditions at an unhurried consultation probably accounts for some findings on the study which Karen Dunnell and I did and which at first sight appear almost contradictory. We found that 52 per cent of the doctors thought they would write fewer prescriptions if they had more time to spend with each patient but that doctors with relatively few patients wrote more prescriptions per patient than those with larger lists. One plausible explanation for the last finding is that doctors looking after small numbers of patients spend more time with them and in doing so find out about more conditions for which they prescribe more medicines. More time, therefore, leads to a greater number of prescriptions per patient even though it may lead on occasion to a doctor talking or listening to a patient rather than prescribing a drug. In our current study we plan to look at the relationship between the length of the consultations, the numbers of problems discussed and not discussed, and prescribing.

THE CHOICE OF TREATMENT: DOCTOR OR DRUG

The concept of the doctor as a form of treatment or 'drug' has been discussed by Balint (21). A number of doctors on our recent study saw the doctor or a drug as alternatives in certain situations.

A doctor thought one patient had a mild depression. The man was not given any medicine for this as the doctor felt that what he needed was "a dose of doctor". The doctor said he was worried about this patient, felt he was very dependent on the doctor and might take an overdose of aspirin one day: "He would if I rejected him." For another patient the doctor said he was prescribing himself rather than barbiturates. He had refused these at the previous consultation and asked the patient to come back and see him again. "She might take in that I'm prepared to see her though not to give her the barbiturates."

But as Shapiro (22) has pointed out: "Some patients, because of difficulty in acknowledging dependency needs, may be incapable of expressing a need for help in any other way than to request and take medicine."

For some patients medicines can reinforce the 'doctor-drug' and the ritual of medicine-taking can give the patient 'reassuring reminders' of the doctor. In what circumstances does the doctor prescribe a dose of himself rather than of a drug? Is he more likely to do this when he finds a patient easy to talk to and when he enjoys seeing the patient? Our findings suggest that giving or not giving a prescription was unrelated to whether he enjoyed seeing the patient² but that fewer prescriptions were given when the doctor found the patient easy to talk to (an average of 1.7) than when he did not (an average of 2.3).³ When the consultation results in a prescription, is the doctor any more or any less likely to regard it as satisfactory then when it does not? We found that an average of 1.3 prescriptions were given when he regarded the consultation as 'very satisfactory, 1.9 when he thought it 'fairly satisfactory'; and 2.3 when he thought it 'less satisfactory.' Possibly the doctors we studied felt prescriptions were less satisfactory than other forms of treatment.

THE CHOICE OF DRUG

One important factor in the choice of drug is that the doctor needs to believe in its efficacy. As Freidson (3) says: "The practitioner is likely to have to believe in what he is doing in order to practice — to believe that what he does does good rather than harm, and that what he does makes the difference between success and failure rather than no difference at all."

A doctor's belief in a drug may reinforce its effect, but drugs, even inactive ones, may also potentiate the effect of the doctor. And of course some doctors prescribe placebos deliberately, recognizing the power of the placebo effect. This is another aspect of the consultation greatly influenced by the patient-doctor relationship. "The doctor's relationship to the patient is basic to an understanding of the placebo effect. The interested doctor who imparts confidence, who is friendly and reassuring to patients, who performs a thorough examination and who is not anxious, conflicted or guilty about the patient or his treatment, is more likely to elicit positive placebo reactions." (22)

² Question: Do you enjoy seeing him?

³ Question: Do you find (—————) an easy person to talk to, or is it difficult to discuss his problem with him?

One of the doctors on our study had prescribed nine drugs for the five patients studied but he reckoned that only two had any pharmacological value. Another doctor on our study says he uses two placebos quite frequently: one which he describes as 'nice' and the cheapest in the British Formulary consists of ascorbic acid; the other 'nasty' one is a gentian mixture. He feels there is little range of placebos available but finds them useful because "most diseases are non-curable and you should not kid yourself you can alter their course" but people often respond to a placebo and to a change of drugs. He finds that most patients "prefer the nasty placebo." Possibly this reflects a belief engendered by the Puritan ethic that medicine has to be nasty if it is to do you good.

This doctor had prescribed placebos at two of the five study consultations — one nice and one nasty. But both patients were taking or had been given other prescribed medicines. The patient who was given the nice placebo described it as "a very good tonic. I think it's got in it what I need for anaemia. I had it all through the winter and he's still giving it to me so he must think it's necessary to take it." (Although her anaemia no longer bothered her.) She was also given a prescription for amytal, for her nerves. The wife of the other patient had asked the doctor if he had anything to cheer her husband up as he was a misery. He was given the nasty tonic with a bit of phenobarbitone, but was also taking an indigestion remedy and sleeping tablets prescribed by the doctor. The prescribing appears pragmatic. Quoting Freidson (3) again: "Perhaps because of his action-orientation, perhaps because of the complexity and variety of the concrete, the practitioner is a fairly crude pragmatist. The clinician is prone in time to trust his own accumulation of personal first-hand experience in preference to abstract principle or 'book knowledge'." This doctor was certainly aware that he was acting pragmatically and felt much more research was needed in this field. A third doctor said, "I'm not a tonic doctor and I make that quite clear from the beginning."

What of the patient's influence and expectations? Four-fifths of the elderly patients on our recent study said they expected or hoped to be given a prescription and only one in seven was not given one. Half of those not expecting any were given one; nineteen out of twenty of the others.

In addition to the case previously mentioned when the patient's wife had asked for something to cheer him up, there were other instances in which the patient's wishes, or the doctor's perceptions of them, had influenced the prescription. One woman said: "I think all people my age should take vitamin tablets" and later "Doctor _____ thinks you should take them at my age"; while the doctor said: "Vitamin capsules make her feel good. They're a placebo and she likes them. She was on them a long time ago and she thought they did her good." Another was given "algipan to rub in because they love it. She was very pleased about the algipan — as much as to say 'at last some sensible advice'."

Sometimes the doctor did not accede to patients' requests — like the one already mentioned who refused to prescribe barbiturates. The doctor had given the patient some other drugs which she had vomited and he interpreted this as a rejection of his medicine. Another request, for sleeping tablets, was quite explicit but had apparently been ignored by the doctor. When the doctor was asked about this later he could not recall whether he had ignored it deliberately or not. Another patient said at the interview beforehand that she hoped the doctor would give her "something to buck me up." She was not given a tonic but the doctor gave her a certificate which recommended rehousing and suggested a different flat might help her 'nerves'.

An illustration of the way prescribing can be a compromise agreed by patient and doctor came from a patient who maintained, when asked if he hoped he would get a prescription, "The doctor decides that, not me. If I'm alright he'll give me nothing." But the doctor classified three of this patient's six prescriptions as 'his' and three as 'mine'. "He's one of the few who has barbiturates. He says it's the only thing that gives him sound sleep. Ephedrine tablets are very important to him. I think they are useless. When he first came I wasn't going to give him barbiturates. I tried others which were useless — then Mogadon. Then I accepted barbiturates. It's an amicable arrangement."

In our earlier study (11) we found that more middle-class than working-class people had taken sedatives, although there were no class differences in the proportion reporting 'sleeplessness' or 'nerves' or 'depression' or 'irritability.' When asked a hypothetical question about what they would do about "a constant feeling of depression for about three weeks" and "difficulty sleeping for about a week" working-class people more often than middle-class thought they would consult a doctor. We concluded that the reason for the difference in the proportions taking sedatives therefore lay in the consulting room. Once there, middle-class people may communicate their demands and anxieties more effectively to the doctor or the doctor may respond to their symptoms differently. To explore this we need an analysis of what goes on at consultations with working- and middle-class patients. Unfortunately, the numbers on our more recent study will probably not be large enough to throw much light on this.

REPEAT PRESCRIPTIONS

Many of the prescriptions given in general practice — around two-thirds (11) — are repeats for drugs that have been prescribed before. In our present study confined to people aged 65 or more and biased towards the frequent attenders, we expected the proportion to be higher. Three-quarters of the prescriptions were repeats. Obviously chronic illnesses are more likely than acute ones to result in repeat prescriptions. But repeat prescribing can have other functions. It can legitimize regular contact with the doctor. Also it enables the doctor to control the frequency of consultations. If a patient is given a prescription which lasts for four weeks he may be discouraged from returning in two weeks. The doctor can see the patient regularly but not too frequently. A repeat prescription for a medicine can ensure a regular dose of doctor. A patient may be more hesitant to return if not given a reason he can readily accept. As one doctor said about a patient, "It offers her a regular and legitimate occasion to come and see me — gives some structure to her life and she feels someone is bothering."

The doctor or the patient may not like the uncertainty of not having a time limit fixed by the running out of a prescription. Of course repeat prescriptions may be issued without a personal contact between the doctor and the patient but it still gives the opportunity for the doctor to review the situation, to have some tenuous contact and to retain some power over the patient. A doctor talking about one of his patients said: "I haven't put her on a prescription card. I wonder why? It's possibly because I enjoy seeing her or I thought I ought to maintain contact."

Another patient in our current study came to see the doctor regularly every two months to collect a prescription for pills for his heart trouble. The doctor felt he needed support and reassurance and this regular contact gave him the opportunity to provide it. During the interview with us the patient said he had asked if he could go longer than two

months but the doctor was against this. The patient may have wanted to demonstrate his independence to us. Another possible explanation is that doctors sometimes feel a need to be needed.

TAKING THE MEDICINE

Several studies have shown that many patients do not follow the advice doctors give them (23, 24, 25, 26). Not surprisingly most studies which depend on data from patients suggest a much higher acceptance of the drugs prescribed by their doctors. In our 1969 study (11) the proportion of prescriptions not tried at all appeared to be between 2 per cent and 5 per cent. Of the medicines tried at all the interviewees said they took 80 per cent exactly as advised, 19 per cent less than advised, and about 1 per cent more than advised. In the more recent study too, the majority, 56 per cent, said they took the medicine exactly as the doctor advised, but 24 per cent said they took rather less, 12 per cent that they took more and 18 per cent were uncertain what he had advised.⁴ Apparently most people like to think that they comply with the doctor's advice. On the earlier study (11) we asked them which of two descriptions was most like them — "Doctors don't know everything about you, so I don't always do exactly what they advise" or, "I always try to do exactly what the doctor advises even if it is not very pleasant or easy." Most people, 86 per cent, thought they were more like the second.

But Gordis, Markowitz and Lilienfeld (27) found that in the group of patients they studied 69 to 73 per cent would be considered compliers from the histories given by the patients or their mothers, but in fact only 33 to 42 per cent were indeed compliers as shown by urine tests.

The doctors on our current study felt that over three-quarters of the patients had taken in all the instructions they had given and would follow them; they thought one in seven had understood the instructions but were uncertain if they would follow them and that one in ten had only taken in some of the instructions.

To some extent it seems a game that both doctors and patients play: assuming that the doctor's advice is understood, accepted and will be carried out. It is the terms on which their relationship is built. Each is in a way flattering the other or boosting his ego by this assumption. To reject the doctor's advice or not follow his instructions, or to admit to someone like us that this has happened, might undermine the relationship.

One patient on our current study had been prescribed antibiotics. Instructions were reported by the patient "Four times a day and not to miss any." The doctor expected her to follow his instructions "to the letter". He explained "She's a bit frightened of me." At the follow-up she said, "If I take them four times a day I get heartburn. I've been dodging them a few days and taking two a day. I'll have to (finish them) before I see him again. . . The doctor prescribes but he's not to know whether it will suit you."

Factors which may influence patients in following advice or instructions are their perceptions of their vulnerability (28), and the amount of information the doctor gives them — those given little information being less likely to comply (29). Studies have also suggested that those who have multiple drugs prescribed are less likely to take them as prescribed (30, 31) and the longer the patient has had a disease the less likely he is to follow a prescribed regimen for it (32). The patient-doctor relationship may have little or no effect on the last of these but will on the others.

⁴The questions asked on the two studies were not comparable and neither were the samples of patients.

IN CONCLUSION

This paper has dealt with some of the ways in which the patient-doctor relationship may affect the perception of ill-health, the action taken by a patient when he perceives himself to be ill, the way in which the illness is presented, the doctor's action, the choice of drug, and whether the drug is taken or not.

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The Family Doctor's Role in Psychotropic Drug Use

Peter A. Parish¹

Any discussion about drugs which alter mood is usually charged with emotion and results in an inevitable process of polarization. But whilst such discussions take place the family doctor is faced each day with patients seeking relief from symptoms of stress. It is from such experience that I wish to examine the family doctor's role in the medical use of psychotropic drugs.

The term "psychotropic" may be applied to any drug which affects the brain, producing an alteration in mood, consciousness, or other psychological or behavioural functions. Most doctors in the United Kingdom restrict the term to five groups of drugs which appear in the drug classification of the Department of Health and Social Security (1). These are barbiturate hypnotics, non-barbiturate hypnotics, tranquillisers, antidepressants, and stimulant and appetite suppressants. The tranquilliser group includes "minor" tranquillisers used mainly to treat anxiety and tension in patients labelled as suffering from psychoneuroses, and the "major" tranquillisers which are used principally to treat patients labelled as suffering from psychoses. There is, of course much overlap.

The medical use of psychotropic drugs describes their use for generally accepted medical reasons, usually under medical supervision (2). Since some observers regard the reasons for the use of these drugs by doctors as not always medical (3), we might more accurately say their use is under the control of the medical profession as their manufacture is under the control of the pharmaceutical industry.

There is nothing new in a minority having control over the manufacture and supply of various mood altering drugs nor is there anything new in the taking of mood altering drugs: it has been a feature of life on earth since the history of man. It seems that the

¹Medical Sociology Research Centre, University College of Swansea, 36 Hanover Street, Swansea, Glamorgan, Wales.

desire to alter mood is becoming increasingly fashionable however. Man appears to require a pharmacological pillow on which to rest his consciousness and this pillow increases in size each year, receiving its inflation from many sources not the least of which is the medical profession. Its overall and increasing size is unaffected by restrictions which are periodically applied to the use of various drugs; these merely result in changes of preference.

The social aspects of medical use of psychotropic drugs is a popular topic for discussion but of course there are social aspects to the medical use of any drug. The model of prescribed drug use is not simple and linear — doctor to patient. It is complex and dynamic. Drugs are developed, manufactured, produced and supplied by the pharmaceutical industry; they are subjected to controls by government and to political pressures by politicians; they are prescribed by doctors; dispensed by pharmacists; consumed by patients; and in the United Kingdom they are paid for by the tax payer. Thus there are numerous interdependent agencies involved in their use. The critical link between them is the prescribing doctor. It is before this door that patients' expectations and trends in their demands, industry's promotion, pharmacists' livelihood, and government's concern find a common pathway. Thus prescribing and taking drugs are social acts with social consequences which should concern all of us. It is right and necessary that medical use of psychotropic drugs should be examined and discussed by persons trained in disciplines other than medicine. For this reason, doctors should not regard examination of their use of such drugs as a threat to their professional autonomy. They ought not to indulge in acts which have social consequences without being accountable for their actions to others in that society.

Is the increasing and almost universal use of mood altering drugs in the Western World related to their increasing availability? Is it the consequence of a fashionable desire to achieve altered status of mood, or is it a consequence of an increase in symptoms of stress produced by life in contemporary society? Certainly, a picture has emerged over the past two decades of people experiencing a multiplicity of physical and mental symptoms from which they seek relief by taking psychotropic drugs prescribed by doctors (4, 5). Yet again, there is nothing new in such treatment. What is new is the *amount* of these drugs being manufactured, the intensity of market competition and sales promotion, the number of different preparations with similar effects, their generous and often indiscriminate prescribing (6), the increase in adverse drug reactions (7), and the increasing number of individuals taking them regularly over many years (8). They are prescribed to patients labelled as suffering from psychological disorders, their consumption increases with advancing age of the individual (6, 8), twice as many women as men take them (4, 6), and their use has not clearly been related to any particular social group (4). Individuals who would not regularly consume alcohol may take psychotropic drugs regularly. However, little is known about differing coping mechanisms in response to stress. We do not know whether people who take prescribed psychotropic drugs smoke or drink alcohol less than those who do not; nor is it known whether those who use such drugs non-medically consult their doctors less or indulge less in alcohol. The different bands of drug use within the whole spectrum of mood altering drug use are not clear. What is certain is that the overall consumption of such drugs increases each year.

Prescribed psychotropic drugs are being used increasingly in many fields of contemporary therapeutics. They are used more frequently than any other group of drugs, and patterns of their use in most Western countries are similar. These suggest international influences resulting in the same proprietary psychotropic preparations appearing amongst

the most frequently prescribed drugs in each country. Detailed comparative data about prescribing trends are difficult to obtain but it is reasonable to suggest that changes observed in psychotropic drug use in England and Wales may give some indication of changes in other Western countries.

ENGLAND AND WALES

In England and Wales psychotropic drugs currently account for about one in five of all prescriptions dispensed by pharmacists under the National Health Service (NHS) (1). They form the largest single group of drugs prescribed in terms of both number of prescriptions and cost. In 1971, 47.8 million prescriptions for psychotropic drugs were dispensed representing some 3,000 million tablets or capsules, about 60 million every week. Forty-one per cent were hypnotics, 38 per cent tranquillisers, 15 per cent antidepressants, and 6 per cent stimulants and appetite suppressants. From 1961 to 1971 there was not only an increase in the number of tablets or capsules per prescription, but there was a 48.8 per cent increase in the number of prescriptions. This consisted of a 23 per cent decrease in the use of barbiturate hypnotics and a 126 per cent increase in non-barbiturate hypnotics. The result was a gradual increase in the overall total of hypnotic drug prescriptions from 18.6 million in 1961, to 21.2 million in 1968, followed by a slight annual reduction to 19.4 million in 1971. After 1965, there was a remarkable shift from the previously popular barbiturate hypnotics to the non-barbiturates Mandrax (methaqualone and diphenhydramine) and Mogadon (nitrazepam), both introduced in 1965. Mandrax became the most widely prescribed hypnotic in 1968, to be superseded by Mogadon in 1969.

The prescribing of stimulant and appetite suppressant drugs decreased by 50 per cent from 1961 to 1971. This may be accounted for by the decreased use of stimulant amphetamines. Of the 3 million prescriptions dispensed in 1971, over one in three was for diethylpropion preparations; a further one in three was for fenfluramine. Tricyclics now account for the majority of antidepressant drug prescriptions which increased from 1.4 million in 1961 to 7.1 million in 1971, replacing the mono-amine oxidase inhibitors as drugs of first choice in the treatment of disorders labelled as depression. From 1961 to 1971, there was a 197 per cent increase in the prescribing of tranquillisers from 6.2 million to 18.4 million. This includes a rapid increase of 7.5 million since 1965 due mainly to increased prescription of two proprietary benzodiazepine minor tranquillisers: Librium (chlordiazepoxide) and Valium (diazepam). In England and Wales then the prescribing of three brand name preparations (Librium, Valium and Mogadon) made the greatest contribution to the overall increase in the number of psychotropic drug prescriptions from 1961 to 1971. All three are benzodiazepines with similar pharmacological effects and are manufactured by the same company. In spite of this, Librium and Valium are marketed as minor tranquillisers and are used to treat symptoms of anxiety, whereas Mogadon is marketed as a hypnotic.

In the UK, benzodiazepines are now accepted as drugs of choice in the treatment of anxiety. Yet despite their cost and success they have never been subjected to randomised controlled clinical trials (9), and probably never will be. This is because of the difficulty in defining anxiety and its response to drug treatment. Furthermore, such trials take about five years to complete, in which time new chemical variations will have been launched and heavily promoted. In the treatment of such ill-defined disorders as anxiety,

planned obsolescence of drugs may always be ahead of the results of major clinical trials. Benzodiazepines are well established and yet one wonders whether prescribing doctors apply any discretionary criteria to their use at all. Certainly, examination of their prescribing suggests that they are being used to treat patients whose situations call more for social change than chemical change (10). But, of course, this sort of indication for the use of such drugs has never been neglected in their sales promotion.

These observations apply to the minor tranquillisers but not necessarily to the major tranquillisers and antidepressant drugs. For example, there is ample evidence that the major tranquillisers (if used appropriately) are of real value in treating psychoses. They relieve disturbing symptoms, reduce the risk of hospitalisation and prevent relapses (11). Equally, there is evidence that the antidepressant drugs if used appropriately benefit depressed patients greatly. These drugs in particular have brought family doctors into the field of psychiatric treatment. They effectively relieve the symptoms which previously interfered with the patient's ability to cope with his everyday existence. They make life bearable for him (and his relatives), reduce hospitalisation and prevent relapse (11). As for stimulants and appetite suppressants (amphetamines and related compounds) most authoritative opinion does not support their use in the treatment of depression and regards the use of drugs to suppress appetite as trivial in the treatment of obesity (12, 13).

The medical use of psychotropic drugs in England and Wales, therefore, suggests both distinctive trends in the type of psychotropic drugs prescribed and a steady increase in their prescription. Some regard these trends as a step in the right direction — that is, towards the increase in use of antidepressant drugs and the decrease in use of barbiturates and amphetamines. Some observers suggest that drugs are being used instead of time: that it is easier to give a prescription than to give advice and that it is easier to take a pill than take advice. This criticism is often aimed at the British National Health Service and yet in countries where private medicine operates and where patients are given more time, the prescribing of these drugs appears similar (5). It is also claimed that because older doctors received no formal training in learning to manage the burden of mental disorders and common anxieties which exist in the community, they resort to pharmacotherapy rather than psychotherapy. Yet the prescribing of these drugs appears to be higher amongst doctors in their first few years in practice (14) and no less amongst doctors with special interests in psychological disorders (6, 8). The suggestion that more time spent between doctor and patient would result in a reduction in drug use is not necessarily valid: it not only presumes that the family doctor can provide psychotherapy, it also presumes that superficial psychotherapy is effective. Other observers take a puritanical view and consider it a "weakness" to resort to psychotropic drugs: but these observers accept palliative and long term drug treatments of physical disorders. A few consider their use as a threat to changes in society, *i.e.*, drugged patients tolerate the intolerable and therefore do not agitate for change. However, by their use of these drugs, doctors clearly define to patients a model for dealing with certain symptoms produced by unpleasant situations. Doctors' prescribing habits therefore influence patients' expectations which subsequently determine demands. These go in fashions: bromides, barbiturates, amphetamines, tranquillisers and antidepressants. Along with changes in drug fashions, go changes in diagnostic labelling. These days, doctors will seldom talk about neurasthenia or nervous debility; they prefer to talk about anxiety and depression. But of course coping mechanisms may have changed as symptoms of stress have become defined and re-defined as requiring drug "treatment." The threshold of tolerance of "feelings" may therefore have changed resulting in a greater demand for "relief." Certainly, symptomatic treatment has increased,

but in part this may be related to changes in patterns of disease. As morbidity and mortality from infectious diseases and physical deprivation decrease, so symptoms of social and mental problems appear to be exposed (15). Defined symptoms of psychological disorders are often insidious and run a protracted and episodic course. Many patients now seek relief from such symptoms and present to their doctor regularly over time and it is here, because of the availability of psychotropic drugs, that patients are labelled "psychological" and treated with drugs.

In addition to a possible change in the threshold of tolerance to feelings, the number of symptoms recognised as psychological has increased dramatically over the past two decades. This has coincided with the use of psychiatric check lists and inventories so that there is now hardly a physical or mental symptom which may not be regarded as "psychological" indicating the need for psychotropic drug treatment. In addition, drug companies have intensively and systematically taken everyday social situations and medical situations and indicated that such situations produce stress. At one and the same time, they have defined the symptoms of stress and the need to treat these symptoms with psychotropic drugs.

We are now in such a position that many doctors diagnose psychological disorders by their patients' response to psychotropic drugs. For example, depression which responds to tricyclic antidepressant drugs is called endogenous depression; if it does not, it is called neurotic. Some neurotic depressions respond to mono-amine oxidase inhibitors and this confirms that the patients were suffering from neurotic depression. Patients with anxiety-phobic states may respond to antidepressant drugs and so these disorders are called atypical depressions. If a patient, suffering from symptoms on which a label cannot be placed, responds to antidepressant drugs, he is said to be suffering from masked depression.

However, all this may not matter provided the patient benefits. It does point up our present lack of knowledge about psychological disorders and their treatment. It also shows that antidepressant drugs relieve many physical and mental symptoms and that the term antidepressant may be much too narrow. It also highlights some of the pitfalls in assessing psychotropic drug treatments for it must always be remembered that the healing process is surrounded by mystification, the consultation having a mystique about it which may be beneficial to patient and doctor. For example, two in five patients respond to placebo treatment, and numerous non-drug factors influence response (16). These factors make evaluation of psychotropic drug treatment in the individual especially difficult and often impossible. Therefore accepting the mystique, accepting that recovery often or sometimes takes place not because of treatment but in spite of it, and accepting that it is often impossible to rationalise in medical scientific terms the "irrational" element in medicine, by what sort of criteria may the medical use of psychotropic drugs by doctors be judged?

Some social scientists would question whether the use of psychotropic drugs is of benefit. They would like to see the mystique stripped away. They see the use of such mind-active drugs as merely patching up "the cracks in a crumbling society." They see the only real solution in an "alternative society." Meanwhile the family doctor, in his caring role, has to get on with his job. He realises that many of his patients are suffering from symptoms produced by social stress and therefore he attempts to modify the patient's reactions knowing that he cannot modify the patient's environment because of factors beyond the control of both the patient and himself. Is it, therefore, wrong for him to give sleep to the wakeful, to calm the tense, to lift the mood of the depressed and give energy

to the exhausted? Is it wrong of him to provide a crutch (albeit chemical) for those of his patients who seek help because they are finding it difficult to cope with the stresses and strains of their everyday living? In itself, it can hardly be considered "wrong." What the doctor must realise is that in so prescribing he is curing nothing. In this context, however, it is well to remember that mental pains cause as much distress as physical pains. Their being less understood does not make their relief any less justifiable. Cure is also rare in physical disease, most treatments being palliative: but such treatments are accepted and expected. Should they not be equally accepted in psychological disorders? That many treatments in contemporary medicine are palliative raises questions that go well beyond the scope of this paper, as does the observation that maximum benefit for the individual may not be the same as providing maximum benefit for the majority. This involves discussion about the relative merits of individual and community care and again are outside the scope of this paper.

What guidelines then can be offered to the family doctor? Certain medical criteria may be applied to the prescribing of psychotropic drugs which although ideal, may help. These are that prescribing doctors ought to attempt to be responsible and rational in their use of drugs (17). To be responsible the family doctor should be answerable for his actions to his peers and patients and also morally accountable (note his role in the thalidomide tragedy). He ought to be aware of a drug's effects and dangers. He ought to keep adequate records, supervise the issuing of prescriptions, provide accurate instructions to the dispensing pharmacist, and inform the patient. In short, he must attempt to have adequate knowledge of his patient and the drugs he is prescribing.

Rational drug therapy preferably ought to be sensible and not extravagant, within the limits of the values and beliefs in contemporary Western therapeutics. It should be based on what may be tested by ordinary canons of scientific enquiry of drug effectiveness allowing for the mystification which surrounds the healing process. However, in everyday practice, the family doctor has to match this ideal of rational prescribing against the reality of inadequate knowledge of the patient and his disorders.

There are four medical criteria which may be considered to form rational prescribing. These are that drug treatments should be appropriate, effective, safe for the patient, and economical. Appropriate drug treatment is that which will benefit the patient most. This must take into consideration the fact that the patient, his symptoms, and his environment are in a constant state of change. Any of these may alter over time: a change in the patient's family situation or work situation may alter his response and therefore his symptoms.

To be effective a drug should produce proper and intended effects. That is, it should relieve a symptom or alter the natural history of a particular disorder for the better. Yet if the term "effective" is applied scientifically to the use of drugs, it should indicate a research result of "treatment" examined by randomised controlled trials at different centres; but very few frequently prescribed psychotropic drugs have been tested by such methods. Here is the dilemma in the medical use of psychotropic drugs. How does one measure objectively such subjective feelings as mood? Does the absence of such scientific evidence mean that most psychotropic drug treatments are ineffective in terms of benefit to the patient?

The prescribing doctor frequently associates any improvement in his patient's condition (which may be simply not returning to the doctor's office) with the medication he has prescribed. The treatment destiny of others suffering from similar disorders is thus determined and a prescribing habit is developed which is based on no more than an

assumption. This habit reinforces the physician's beliefs that his medication is effective. Yet he may not even know whether the patient took the drugs as directed. Unused drug collection programmes (18, 19) indicate that huge quantities of surplus prescribed psychotropic drugs accumulate in patients' homes, and drug use studies show that the patient has a considerable autonomy when it comes to taking prescribed drugs (20).

Safety must always be considered. The medical use of drugs should preferably cause some improvement in the patient, yet the diseases of medical progress are to a great extent predictable and preventable complications of treatment. It has been estimated that 10 per cent of patients develop adverse drug reactions (21) and 3 to 5 per cent of hospital admissions are caused from such reactions (22). Eighteen to thirty per cent of patients in hospital suffer from adverse drug reactions (22) and 30 per cent of patients admitted for a drug reaction have a reaction to the same or another drug during the same hospitalisation (23). These are in addition to drug overdoses which account for 10 per cent of medical admissions (24). An increasing proportion of these adverse drug reactions are being caused by psychotropic drugs (25).

Unfortunately, drug reactions are often not recognized partly because doctors seem reluctant to think that their treatment has contributed to the patient's disability. It is easier to attribute the patient's new symptom to an extension of the underlying disorder than to the drug treatment. This leads to an additional hazard: the tendency for doctors to treat the adverse effects of one drug with another drug which may itself produce further adverse effects. The hazards of multiple drug prescribing are not well recognized particularly in the drug treatment of certain groups such as babies, pregnant women, the elderly, and the debilitated. The most important result of the thalidomide tragedy was the acceptance that drug reactions are a serious hazard.

In the field of psychotropic drug prescribing there has been no work on cost effectiveness. Most interest has centred around the increasing use of brand name products, many of which represent no advance over already established drugs. The fundamental question on cost has been whether the prescribing doctor should choose the cheapest product from amongst a group with equal efficacy. The industry's answer is centred around what is called therapeutic equivalence: this means that the way a drug is prepared and formulated may affect its availability to the body and therefore its effectiveness. The industry stresses the high standard of quality control which ensures predictable availability and holds that therapeutic equivalence is not the same for chemically equivalent drugs. The medical profession is divided in its opinions. Some doctors claim that the whole problem has been grossly exaggerated by industry because of its interest in promoting brand name products as a protection against investments on research and development; others have demonstrated differences among drugs and produced evidence to support the claims of the various drug companies. The arguments on equivalences bring drug prescribing down to very precise limits by assuming that doctors prescribe, and patients take drugs "correctly" — *i.e.* according to strict pharmacological principles — which of course they do not!

If psychotropic drug prescribing is examined in the light of these criteria it appears that doctors are not always responsible and rational in their use of these drugs. Such actions have obvious social implications, but drug prescribing is only part of drug use and so these criteria should not only be applied to the prescriber. It is wrong to isolate him for special criticism: his prescribing should not be judged against criteria which are solely medical. We are all involved in drug use — patients and doctors, politicians and pharmacists, industry and government.

For example, the pharmaceutical industry has played a major part in dictating the fashions of psychotropic drug use. Not only have the past two decades seen what some regard as a revolution in the drug treatment of psychological disorders but there has also been a revolution in drug marketing and sales promotion. The pharmaceutical industry has grown rapidly during this time. Multinational monopolies have developed which now control huge areas of the international pharmaceutical markets. The universality of physical and mental symptoms has provided an expanding market for these companies whose spread appears to have been more dictated by investment than by society's needs (26). Like most manufacturers of consumer goods they have successfully created a need for their products by defining indications for their use (3). The market is flooded with minor chemical variations (what is often referred to as molecular roulette) and promotional gimmicks (e.g. combination products). There are too many preparations of similar drugs. For example, the products produced by Roche and referred to the Monopolies Commission (27) included chlordiazepoxide (Librium) and diazepam (Valium) and 4 chlordiazepoxide combination products, one containing clidinium (a gastro-intestinal antispasmodic); amitriptyline (an antidepressant); pentaerythritol (a drug used to treat angina); and theophylline and ephedrine (used to treat bronchospasm). In identifying products in competition with these products Roche listed 25 therapeutic uses of these reference products. They next identified 38 other groups of drugs used for one or more of these 25 uses and lastly identified 600 products within these 38 groups which they considered to be competitors to their six reference products. So much for innovation in contemporary therapeutics!

In the UK the pharmaceutical industry spends huge sums of money on sales promotion; maintains an active and continuous programme of public relations; is active in the fields of government, industry, professions and news media; sponsors clinical trials and other research; finances non-subscribed literature to doctors; supports professional journals by drug advertising; provides educational services, lunches, dinners, buffets, film shows, hand-outs and gifts; and deploys an enormous sales force which succeeds in a high proportion of face-to-face interviews between sales representatives and prescribing doctors. In addition, it carries out expensive market research, collecting details of prescribers and their prescriptions. Its marketing strategy is intensive and highly competitive. A comment on marketing has been provided by a member of the pharmaceutical industry:

There is a growing opinion, that within the present state of medical and pharmacological knowledge, the ripest plums have already been harvested and that in future it will be increasingly difficult to innovate. . .major advances will be less frequent and competitors' pressures will force companies to market more brands with only minor advantages (28).

These skills of modern marketing are applied to the prescribing doctor and therefore some critics regard him as merely a manipulated agent between producer and consumer. They also point out that the cost of drug treatments are high and so are profits on drugs; patents last too long; and multinational monopolies do not operate in the public interest. But these observations may be applied to most international monopolies and therefore it is difficult to find out whether the critics of the pharmaceutical industry are specifically interested in drug use and its benefits to society, or whether they are politically motivated and are using the pharmaceutical industry as an example of abuses in a capitalist society.

In terms of human welfare, drugs impose important responsibilities on all parties concerned. Society's ill health may be measured in terms of morbidity rates, mortality rates, duration of illness episodes, time lost from work, loss of production, cost of hospitalisation. But how does one even attempt to measure the relief of human suffering achieved by the use of drugs? In monetary terms the cost of the pharmaceutical services is a small fraction of the overall expenditure involved in the process of caring and should, therefore, be viewed in perspective. For example, the cost of the pharmaceutical services to the English and Welsh National Health Service represents about one half of one per cent of the gross national income (29). Yet in 1969-70 taxation on the sales of alcohol accounted for 5.65 per cent of revenue from all sources, and for tobacco in 1969, 7.7 per cent (30).

CONCLUSION

In conclusion, the medical use of psychotropic drugs has social aspects which should concern us all, but is there cause for concern? Of course, the power of control over the production and supply of these drugs by the pharmaceutical industry and the medical profession, respectively, is central to any discussion about their use; but in isolating these for special examination the real issues may be missed. *These issues are about who benefits from the medical use of psychotropic drugs, the risks involved and the alternatives.*

Many observers are well away from the "patient's bedside" and from this position (often criticised by practising doctors) an increasing number are showing concern about the quality of life and about the limits of treatment medicine; but in attacking the pharmaceutical industry, are they not questioning the whole capitalist system? In examining the patient/doctor relationship are they not questioning the role of professionalism and searching for equality? In the widespread medical use of psychotropic drugs are they not fearful that suppression of stress symptoms may delay social change? Are they not questioning the whole value system of contemporary society?

In the meantime, the medical profession, blinkered by its own values and beliefs, will continue to practise palliative medicine; man's search for alterations of mood will continue; the use of mood altering drugs will increase; the pharmaceutical industry, the brewers, tobacco manufacturers, and other manufacturers of mood altering drugs will step up production; and governments will legislate. Whether we will be happier is anybody's guess. One thing is certain, we cannot put the clock back; the future may have to be a compromise between chemical change and social change.

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Family Patterns in Prescriptions of Psychotherapeutic Drugs

Kai Pernanen¹

The family should be of central concern in the field of health sciences. There is an accumulated literature on the family patterns of ill health (1, 15), and of seeing a physician (1, 2), and also on family patterns of mental problems, behavioural disorders, and somatic illnesses (3, 4, 5, 6).

Even when the family is not the statistical unit of analysis or the object of study of interrelationships of health variables within the family, there is implicit recognition of the importance of familial characteristics in many studies in the field. Studies as wide apart as the relationship and utilization of physicians' services and income (7) and the presentation of symptoms and ethnic background (8) at least implicitly acknowledge the importance of familial characteristics.

As a complement to this field of studies, this report will attempt to look at the family as a unit in a descriptive account of the extent of prescriptions for family members and the extent of "availability" of prescribed psychotherapeutic drugs within the family. Secondly, it will look at the possible clustering between different family members in their prescriptions of psychotherapeutic and other types of drugs.

In terms of availability of the drug within the family, the prevalence of use in each family is of importance. The extent of non-medical drug use and/or self-medication of psychotherapeutic drugs for any one member of the family is currently unknown. When we have some idea of the availability of psychotherapeutic drugs within a family, we may be better equipped to assess the actual importance of factors such as alienation in forming the drug-using habits of young people. The acceptance of psychotherapeutic drug-use that

probably occurs when one person in the family, particularly a parent, uses such a drug, is undoubtedly relevant in the etiology of youthful drug-using behaviour.

The relationship in drug-use patterns between various family members depends on a number of factors, only one of which may be morbidity. Thus, our findings on the patterns of prescriptions of psychotherapeutic drugs between family members do not allow further analysis of the clustering found. However, the data do provide suggestions for further study.

THE DATA

The data to be presented were obtained from an outside source; thus the investigator had no control of the variables initially included. However, they do allow us to search for patterns of use between family members. The prescription information was made available by the Green Shield Prescription Plan, which is located in Ontario. Eighty-two per cent of its subscribers live in one county (Essex) in southern Ontario. The members of the plan are employees or retired employees of firms, or members of unions, or union locals which have joined the plan. If the individual subscriber is male, the plan automatically includes his dependents, *i.e.*, the spouse and children (including step-children and legally adopted children) "who are under the age of 19, unmarried and normally reside with and are dependent upon the subscriber" (15). At the option of the subscriber, the coverage can be extended to children who are over the age of 19 but otherwise fulfil the above criteria and "are still attending school, college or university (except for mentally handicapped) and who, in the opinion of the Pharmaceutical Director of Green Shield Plan, are wholly dependent upon the subscriber for support."²

A female subscriber, on the other hand, has the option to enrol in the plan alone or to enrol her entire family, in which case the same rules apply. Every new born or newly adopted child is enrolled upon birth or adoption.

For each prescription there is a dispensing charge of 35 cents to be paid to the pharmacy. If the subscriber resides in an area in which there are no member pharmacies, he will be reimbursed by the Green Shield Plan.

Our original data consisted of all the purchases of prescribed drugs by all the subscribers and their dependents who were in the plan for at least part of the one-year period between April 1, 1970 and March 31, 1971. From this we selected only those families who had been subscribers for a full year and examined their purchases of all types of drugs during that year. The emphasis in our analyses has been on the psychotherapeutic drugs.

The information on the prescription included the date of the purchase, the drug name and quantity purchased and the member pharmacy in which it was purchased. In addition, there was information on some characteristics of the purchaser, such as marital status, family role (father, mother, daughter, son), age, the firm of which the subscriber was an employee or the union to which he/she belonged, the date that the person had joined the plan, and family size.

Among the psychotherapeutic drugs, we have examined the major tranquillizers, minor tranquillizers, antidepressants, sedatives and hypnotics, and anorexics or anorexi-ant amphetamines. For comparative purposes, the data on somatic drugs containing psychotherapeutic agents and all other somatic drugs were obtained.

²2-, 3-, and 4-member families does not of course represent necessarily the number of family members in that household. Children over the age of 19 may be residing at home, though they do not fit the criteria for inclusion. Other members of the family (such as grandparents) may be living in the household but are not covered by the Plan.

For the study on family patterns of prescriptions that is reported here, a further delimitation of the population was made. The sample was drawn from families where the subscriber was employed by a large automobile industry. Three types of families were selected. First, families consisting of husband and wife only (3,128 families); they will be referred to as "2-member families." Second, families consisting of husband, wife and one child; there are 1,358 of these "3-member families." Third, families consisting of husband, wife and two children ("4-member families"), of which there are 1,861 in our study. The sample sizes are adequate for most of our purposes.

The reason for selecting a sample from one industry instead of all industries is that we wanted a sample that was homogeneous in one respect. As happens frequently, what we may have gained in terms of controlling for a set of extraneous variables we have lost in generalizability of our findings. It should be stressed that there is no certainty that these findings would be replicated in a general population sample of families. However, because the plan covers everyone within the industry from chief executives to unskilled workers, the data may at least be generalizable to comparable industries.³

Availability of Psychotherapeutic Drugs Within the Family

Tables I through IX show the distribution of family prescriptions of drugs over the purchase year. The Tables also show the percentage of families where at least one person received one or more prescriptions over the purchase year, and for 3- and 4-member families, the percentage of families where one child (in 3-member families), or one or two children (in 4-member families), received at least one prescription over the purchase year.

There is, of course, nothing very startling in the findings shown in these Tables that the percentages rise with increasing family size. The exception to the pattern occurs for sedatives (Table IV) and this reversal of the trend affects the total for all psychotherapeutic drugs. The high percentage of sedatives in 2-member families is probably due to the greater proportion of old people in 2-member families.⁴ Preliminary data from a study of the prevalence of use of psychotherapeutic drugs in the same prescription insurance plan population shows that 19 per cent of males and 30 per cent of females in the age group 65 and over had one or more prescriptions of sedatives or hypnotics over the purchase year, whereas, in the age group of 20 to 49 the percentages were approximately 7 and 13 (13). Although there are presumably a number of young couples in our 2-member families who have not yet begun their families, it does not seem to counter-balance the higher prevalence of sedative prescriptions.

If there is any basis for generalization from our sample, it appears that over half of the families in a largely urban industrial population contain at least one member receiving prescribed psychotherapeutic drugs at some time during one year. In terms of availability for extramedical use by other family members, this is a rather high figure. In terms of acceptance of use of mood-modifying drugs, a great deal depends on how much general knowledge other members of the family have of the type of drug that is being used. For

³The problems of validity of data on psychotropic drug use have been dealt with by Parry (11) in his study of the validity of survey reports of drug consumption. He found some segments of the population under-reporting psychotropic drug use. Prescription data, while avoiding these problems, limit our information. They only provide a knowledge of the intention of the prescriber rather than the actual pattern of the consumption of the drug. Although prescription data do not prove actual consumption, they do at least do away with problems of under- or over-reporting use.

⁴It is likely that those couples who have not yet begun families and those whose families have reached maturity, i.e. the young and the over-fifties, are over-represented in the 2-member families and to a lesser extent in the 3-member families.

TABLE I

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR MAJOR TRANQUILLIZERS
DURING THE PURCHASE YEAR BY HUSBAND-WIFE COMBINATION
AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	2,894	92.5	1,245	91.7	1,721	92.5
Husband	78	2.5	37	2.7	47	2.5
Wife	139	4.4	72	5.3	86	4.6
Both	17	0.5	4	0.3	7	0.4
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	28	2.1	71	3.8
Families in which a member got prescription	234	7.5	134	9.9	197	10.6

TABLE II

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR MINOR TRANQUILLIZERS
DURING THE PURCHASE YEAR BY HUSBAND-WIFE COMBINATION
AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	2,100	67.1	926	68.2	1,187	63.8
Husband	267	8.5	116	8.5	150	8.1
Wife	556	17.8	246	18.1	407	21.9
Both	205	6.6	70	5.2	117	6.3
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	42	3.1	98	5.3
Families in which a member got prescription	1,028	32.9	451	33.2	713	38.3

TABLE III

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR ANTIDEPRESSANTS
DURING THE PURCHASE YEAR BY HUSBAND-WIFE COMBINATION
AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	2,819	90.1	1,233	90.8	1,657	89.0
Husband	93	3.0	29	2.1	52	2.8
Wife	194	6.2	80	5.9	139	7.5
Both	22	0.7	16	1.2	13	0.7
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	19	1.4	38	2.0
Families in which a member got prescription	309	9.9	137	10.1	228	12.3

TABLE IV

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR SEDATIVES OR HYPNOTICS
DURING THE PURCHASE YEAR BY HUSBAND-WIFE COMBINATION
AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	2,282	73.0	1,114	82.0	1,551	83.3
Husband	233	7.4	76	5.6	90	4.8
Wife	423	13.5	141	10.4	187	10.0
Both	190	6.1	27	1.9	33	1.8
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	22	1.6	51	2.7
Families in which a member got prescription	846	27.0	262	19.3	346	18.6

example, does the youngster in the family know that a parent is using a drug, why it was prescribed, what it was intended to do? Does he observe a change in behaviour as a result of the drug used? And finally, how does it affect his conception of drug use for himself? Further, does the use of a minor tranquilizer, for example, by one of the marital partners induce the spouse to try the same drug extramedically and perhaps turn to the doctor more readily when he feels anxious or tense in coping with some difficult situation on his own?

The answers to these and related questions can only come from more specific research designs. Our information relates only to the purchase of prescribed drugs and we have no information on the factors that have gone into prescribing decisions. To date no studies have dealt with the mechanisms by which psychotherapeutic drugs come to be accepted by patients as a solution to their problems, and the effect of that use on the acceptance of drugs by other family members.

The Association of Psychotherapeutic Prescriptions Between Family Members

The influence of acceptance of use within the family would show up in positive relationships between family members in their psychotherapeutic drug use. There are many possible explanations for a positive relationship between family members or clusterings of family members.

First of all, there are some data available on the prescribing habits of physicians indicating a wide range of patterns of prescribing. We can assume that as long as there is a tendency for family members to visit the same physician, the prescribing habits of the physician will lead to more or less use by the entire family. There may also be factors that determine the physician's perception of the entire family and affect the nature of his interaction with them. It has, for example, been shown that some physicians are more prone to give prescriptions for psychotherapeutic drugs to patients of lower socio-economic status (10). There could thus be an association between prescriptions of spouses wholly independent of any influence of family members or family characteristics. It was originally thought that age differences between spouses might be a relevant variable. Table X⁵ examines drug use in this way and shows that there is no clear-cut tendency for spouses of the same age to be more likely to use drugs than spouses with a greater age gap. For psychotherapeutic drugs the tendency is closer to the opposite, although minimally so.

Secondly, there are many factors that can contribute to a high or low use of physicians' services by a family. Other studies indicate that family income has an effect on utilization of physicians' services (2, 7, 11). The recognition of need for physicians' services may be more alike within a family than between families. Factors such as education, family background and previous experience with symptoms would likely affect the choice of treatment. Even preventive visits to the physician can lead to clustering if they are done together, as often happens with mother and child or if they are clustered in time (1, 5).

⁵ A note on the use of statistical methods is in place here. The contingency coefficient is a somewhat misleading measure of association, since its maximum value for 2 x 2 Tables is 0.707. For the purpose of testing the significance of an association, however, it is very convenient since it is based on the X^2 -measure. Moreover, for the purpose of comparing contingency coefficients the fact that the maximum value is less than 1 has of course no relevance. The X^2 -values (and the contingency coefficients) have been corrected for continuity.

TABLE V

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR ANOREXIANTS OR
ANOREXIANT AMPHETAMINES DURING THE PURCHASE YEAR BY
HUSBAND-WIFE COMBINATION AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	2,758	88.2	1,146	84.4	1,575	84.6
Husband	58	1.8	44	3.2	56	3.0
Wife	256	8.2	145	10.7	194	10.4
Both	56	1.8	23	1.7	36	1.9
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	12	0.9	23	1.2
Families in which a member got prescription	370	11.8	213	15.7	295	15.9

TABLE VI

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR ANY TYPE OF
PSYCHOTHERAPEUTIC DRUG DURING THE PURCHASE YEAR BY
HUSBAND-WIFE COMBINATION AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	1,400	44.7	662	48.7	859	46.2
Husband	343	11.0	141	10.4	182	9.8
Wife	835	26.7	378	27.8	539	29.0
Both	550	17.6	177	13.0	281	15.1
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	112	8.2	240	12.9
Families in which a member got prescription	1,728	55.3	730	53.8	1,055	56.7

TABLE VII

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR ALL DRUGS
DURING THE PURCHASE YEAR BY HUSBAND-WIFE COMBINATION
AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	250	8.0	107	7.9	109	5.9
Husband	326	10.4	132	9.7	162	8.7
Wife	521	16.7	236	17.4	318	17.1
Both	2,031	64.9	883	65.0	1,272	68.4
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	1,014	74.7	1,627	87.4
Families in which a member got prescription	2,878	92.0	1,298	95.6	1,817	97.6

TABLE VIII

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR SOMATIC DRUGS WITH
PSYCHOTHERAPEUTIC AGENT DURING THE PURCHASE YEAR BY
HUSBAND-WIFE COMBINATION AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	2,031	64.9	880	64.8	1,222	65.7
Husband	338	10.8	173	12.7	218	11.7
Wife	530	16.9	226	16.6	331	17.8
Both	229	7.3	79	5.8	90	4.8
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	82	6.0	182	9.8
Families in which a member got prescription	1,097	35.1	525	38.7	732	39.3

TABLE IX

RECEIPT OF ONE OR MORE PRESCRIPTIONS FOR ALL SOMATIC DRUGS
DURING THE PURCHASE YEAR BY HUSBAND-WIFE COMBINATON
AND SIZE OF FAMILY

Husband-Wife Combination	2 Member		3 Member		4 Member	
	N	%	N	%	N	%
Neither	349	11.2	152	11.2	169	9.1
Husband	392	12.5	162	11.9	231	12.4
Wife	629	20.1	277	20.4	360	19.3
Both	1,758	56.2	767	56.5	1,101	59.2
Total	3,128	100.0	1,358	100.0	1,861	100.0
Families in which a child got prescription	—	—	989	72.8	1,594	85.7
Families in which a member got prescription	2,779	88.8	1,277	94.0	1,799	96.7

Thirdly, it is possible that there is actual clustering in morbidity in mental problems within families. It has been shown in many studies that psychiatric problems and disorders tend to run in families (1, 3, 4, 5). Many stress situations are common to the members of the same family whether they occur within the family (e.g., marital discord), or are the outcome of some external stress factors that affect more than one member of the family (e.g., unemployment).

For drug use figures *in general* and for some specific drug categories, the association can, in time, partly be explained in terms of infectious diseases that spread within families (9). However, this is highly unlikely with psychotherapeutic drugs. Genetic factors could, however, give rise to a clustering of certain drug prescriptions between parents and offspring.

In spite of all these factors that may explain any clustering of prescriptions within families, a comparison of the strength of associations between the use of various types of drugs for those occupying individual roles within the family may give us additional clues as to factors relevant to drug use. Table XI presents the contingency coefficients of association between the husband and wife each receiving at least one prescription of the various types of drugs. As seen in the previous section, family size had an influence, especially on the extent to which sedatives and hypnotics were prescribed to husband and wife. Table XII shows that family size is a factor in the *association* between husband and wife in prescriptions that they get. The associations are stronger for the 2-member families, especially for the psychotherapeutic drugs and somatic drugs with psychotherapeutic agents.

TABLE X
CONTINGENCY COEFFICIENTS BETWEEN PRESCRIPTIONS FOR HUSBAND AND WIFE
BY DRUG TYPE, FAMILY SIZE, AND AGE DIFFERENCE BETWEEN SPOUSES

Drug Type	2-Member Families		3-Member Families		4-Member Families	
	Age Difference 0-5 Years (N=2248)	Age Difference 6+ Years (N=880)	Age Difference 0-5 Years (N=1103)	Age Difference 6+ Years (N=255)	Age Difference 0-5 Years (N=1508)	Age Difference 6+ Years (N=353)
Major tranquilizers	*	*	*	*	*	*
Minor tranquilizers	0.18	0.18	0.12	0.18	0.13	0.16
Antidepressants	0.09	0.08	*	*	*	*
Sedatives or hypnotics	0.23	0.28	0.09	(0.21)	0.10	(0.14)
Anorexiant amphetamines or anorexians	0.22	0.29	0.16	*	0.20	*
Any type of psycho- therapeutic drug	0.21	0.23	0.16	0.15	0.18	0.21
Somatic drugs with psychotherapeutic agent	0.16	0.19	0.12	0.00	0.06	0.11
All somatic drugs	0.20	0.16	0.18	0.25	0.17	0.06
All drugs	0.23	0.14	0.19	0.22	0.19	0.03

*The expected frequencies were too small to allow the use of contingency coefficients.
All coefficients within parentheses should be interpreted with caution since expected frequencies are below 5.

TABLE XI

CONTINGENCY COEFFICIENTS BETWEEN PRESCRIPTIONS FOR HUSBAND AND WIFE
BY DRUG TYPE AND FAMILY SIZE

Drug Type	2-Member Families (N=3128)	3-Member Families (N=1358)	4-Member Families (N=1861)
Major tranquillizers	(0.09)	(0.02)	(0.06)
Minor tranquillizers	0.18	0.13	0.14
Antidepressants	0.09	(0.19)	0.08
Sedatives or hypnotics	0.24	0.12	0.12
Anorexiant amphetamines or anorexiant	0.24	0.14	0.18
Any type of psycho- therapeutic drug	0.21	0.16	0.19
Somatic drugs with psychotherapeutic agent	0.17	0.10	0.07
All somatic drugs	0.19	0.19	0.16
All drugs	0.19	0.20	0.17

All coefficients within parentheses should be interpreted with caution since expected frequencies are below 5 (see Table II).

All coefficients except for major tranquillizers in 3-Member families ($C=0.02$) are significant at the .01 level.

As an indication of the value of examining the clustering of prescriptions for husband and wife, Table XII presents the observed and expected frequencies of both spouses getting one or more prescriptions over the purchase year. It shows that in our sample of 3,128 2-member families there was an excess of 90 spouses getting a prescription of minor tranquillizers. For sedatives or hypnotics there was an excess of 107 spouses, and so on. In these absolute numbers the association between psychotherapeutic drug prescriptions between spouses led to greatest excess for sedatives in the 2-member families and minor tranquillizers in the 3-member and 4-member families.

The stronger association in drug prescriptions between spouses in 2-member families could again be explained in terms of the larger proportion of older couples among families of this size. There are two variables which could possibly explain this. One is the older age, *per se*, a period of higher morbidity for both sexes. Thus one would expect more clustering in populations where older people are over-represented, as in 2-member families. Whereas physicians tend to perceive women's problems as being different from men's problems and therefore prescribe differentially, this may break down somewhat in the case of older people.

TABLE XII

OBSERVED AND EXPECTED FREQUENCIES OF BOTH HUSBAND AND WIFE
GETTING PRESCRIPTION BY DRUG TYPE AND FAMILY SIZE

Type of Drug	2-Member N=3128		3-Member N=1358		4-Member N=1861	
	fo	fe	fo	fe	fo	fe
Major tranquillizers	17	4.7	4	2.3	7	2.7
Minor tranquillizers	205	114.8	70	43.3	117	75.2
Antidepressants	22	7.9	16	3.2	13	5.3
Sedatives or hypnotics	190	82.9	27	12.7	33	14.5
Anorexiant amphetamines or anorexiant	56	11.4	23	8.3	36	11.4
Any type of psycho- therapeutic drug	550	395.4	177	130.0	281	204.0
Somatic drugs with psychotherapeutic agent	229	137.6	79	56.6	90	69.7
All somatic drugs	1,758	1,640.7	767	714.2	1,101	1,045.7
All drugs	2,031	1,923.0	883	836.4	1,272	1,225.2

Older couples, comprising part of the 2-member families, have lived together longer and have thus, if not perhaps grown more alike, at least grown more alike in the cues they see as signs of problems in themselves and each other and also in the way they react to these signs. An older couple may be more likely to use a doctor's services in similar ways and to be more alike in their acceptance of psychotherapeutic drugs.

Table XIII shows that family size as such does not have any explanatory power, at least for 3- and 4-member families. On the other hand, the results indicated in the Table do lend strong support to the explanation relating age of spouses or length of marriage to the association in their drug prescriptions since there is, for all drug types, a higher degree of association in families with older children. However, it could be that older children act less as "buffers" in the interaction between spouses than younger children do. Using these data it is not possible to test which of the interpretations is the more correct. No systematic differences between the drug types are discernible.

TABLE XIII

CONTINGENCY COEFFICIENTS BETWEEN PRESCRIPTIONS FOR HUSBAND AND WIFE
BY DRUG TYPE, FAMILY SIZE AND AGE OF CHILDREN

Drug Type	3-Member Families		4-Member Families	
	Child's Age 0-9 (N=879)	Child's Age 15+ (N=339)	Children's Ages Both 0-9 (N=940)	Children's ^a Ages 10-14 and 15+ or Both 15+ (N=438)
Minor tranquillizers	0.10	0.16	0.08	0.17
Sedatives or hypnotics	0.05	0.20	0.10	0.18
Any type of psycho- therapeutic drug	0.13	0.26	0.18	0.21
Somatic drugs with psychotherapeutic agent	0.09	0.10	0.01	0.11
All somatic drugs	0.15	0.27	0.14	0.18
All drugs	0.16	0.25	0.13	0.23

^aCross tabulations with actual age of parents were not available at the time of printing so that childrens' ages have been used as indicators of the ages of parents. To minimize overlap the age groups at the extremes have been used. The number of families with both children aged 15 and over was too small among 4-member families so that families in which one child was 10-14 and the other 15 and over were included in the analysis. Family size per se is thus not a variable in this Table — the analysis in the two family types should only be seen as replications.

TABLE XIV

CONTINGENCY COEFFICIENTS BETWEEN PRESCRIPTIONS FOR PARENTS AND CHILDREN
BY DRUG TYPE (3-MEMBER FAMILIES)

Drug Type	Mother- Daughter (N=620)	Mother- Son (N=738)	Mother- Child (N=1358)	Father- Daughter (N=620)	Father- Son (N=738)	Father- Child (N=1358)
Minor tranquillizers	*	*	0.10	*	*	0.03
Any psycho- therapeutic drug	0.09	0.14	0.12	0.05	0.08	0.07
Somatic drugs with psychotherapeutic agent	0.02	0.07	0.03	0.00	0.02	0.02
All somatic drugs	0.20	0.26	0.23	0.07	0.15	0.12
All drugs	0.23	0.28	0.26	0.09	0.12	0.11

*The expected frequencies were too small to allow the use of contingency coefficients.

Information on Prescription Patterns between Parents and Children in the 3- and 4-Member Families.

Because there were few prescriptions of psychotherapeutic drugs for children, all the psychotherapeutic drug types except minor tranquilizers had to be omitted from the analysis. There is a much stronger association between mother and child in the use of all the drug types analyzed than between father and child in the 3-member families, as shown in Table XIV. For both parents there is a stronger association with a son in the family than with a daughter. The strongest correlations are for the somatic drugs and the weakest for somatic drugs with psychotherapeutic agent. The rank order in the strength of associations is the following: mother-son, mother-daughter, father-son, father-daughter.

The stronger correlations with the mother could partly be explained by the "mother artifact," that is the mother escorting the child to the physician, combined with the fact that neurotic mothers, who themselves tend to have more physical complaints, also might take their children to a physician on slighter indications (5).

The association between mother and child (Table XIV) does not seem to be any stronger than that between the parents in 3-member families (Table XI). In the 4-member families there is a slight tendency for the fathers' drug prescriptions to be associated more with the drug prescriptions of the older rather than the younger children (Table XV). This tendency is clear for the minor tranquilizers, psychotherapeutic drugs, and somatic drugs with psychotherapeutic agents.

The psychotherapeutic drug prescriptions of the mother are more closely associated with the prescriptions for the older son than the older daughter, whereas the psychotherapeutic drug prescriptions for the father are more closely related to the prescriptions for the older daughter in the family, although the tendency is very slight. For the younger children there is no appreciable difference between mother-son and mother-daughter associations. For the father there is a tendency towards closer association with son than with daughter. The other drugs show a rather disconcerting array of contingency coefficients and the only negative associations in our study — those for somatic drugs with psychotherapeutic agent.

SUMMARY

The sample under study consisted of 3,128 husband-wife families, 1,358 families with spouses and one child, and 1,861 families with spouses and two children covered by the Green Shield Prescription Plan. Information on their filled prescriptions was obtained for a period of one year. In over half of the families one or more persons had a prescription for a psychotherapeutic drug over the year.

Between the family members there was a clustering of prescriptions. The association was, in general, strongest for the somatic drugs. All associations studied for psychotherapeutic drugs were positive.

Associations between husband and wife were strongest for childless couples. Couples with older children were more similar in their prescriptions than those with younger children. There was no great difference in the strength of these associations between spouses with one child and those with two children.

The child in a 3-member family was more similar to the mother than to the father. In these families, however, the associations were between sons and parents rather than daughters and parents.

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Drug Utilization and the Quality of Primary Health Care: A Methodology for Appraisal

John C. Sibley¹

INTRODUCTION

The relationship between the physician's prescription of mood-modifying drugs (M.M.D.) and the incidence of drug dependency in society has frequently been questioned. A number of reports (1, 2, 3, 26) deal with the amount of M.M.D. prescribed by physicians for patients. Additional studies are concerned with such factors as sex differences (4) and socio-economic differences (5) in the use of mood-modifying agents.

These useful studies raise a number of basic issues to be resolved before one can answer the more fundamental question, "Is there a causative relationship between the prescription of M.M.D. and the incidence of drug dependency or addiction?"

For example, does the correct and selective prescription of M.M.D. by a physician practising a high quality of patient care reduce or increase drug dependency in the population under his care? Do we have explicit criteria for the adequate or correct prescribing of M.M.D.? Are there explicit criteria we can use to determine whether a patient with depression is treated adequately or inadequately? The high prevalence of emotional, psychiatric and behavioural problems determines that they must be handled and, in fact, are handled initially at least, in the primary health care system. Furthermore, since many emotional and psychiatric problems present in a somatic model such as peptic ulcer, headache, and fatigue, these issues must be studied within the larger context of the quality of care provided in the primary health care system.

¹Health Sciences Centre, Mc Master University, 1200 Main St. West, Hamilton, Ont. L8S 4J9, Canada.

PRESENT STUDY

The primary purpose of this study was to develop a sensitive, credible and realistic method of assessing the quality of patient care delivered in primary care practice. One component of the study examined the quality of care as it related to drug utilization and the management of depression. We did not attempt to determine the presence or absence of a causative relationship between the prescribing of M.M.D. and the prevalence of drug dependency in the population under study. This study is presented for consideration as a model which might be used by researchers in the field of drug addiction wishing to study the relationship between the quality of primary care and the prevalence of drug dependency.

The stimulus for this present research was a need to provide a framework for testing the hypothesis that the introduction of a trained nurse practitioner as a primary health professional in a family practice would not change the quality of care. It is one of five research studies carried out on an experimental, suburban community practice (6). A related study (7) dealing with the end-result analysis of the emotional, physical, and social function as a measurement of patient care in the same practice will be referred to briefly. The major component of this presentation, therefore, will deal with a method of appraisal of quality of care followed by a brief presentation of the results obtained in its first application in the Burlington Nurse Practitioner Trial.

Three approaches were used to assess the quality of care. First, the use of indicator conditions; second, the study of drug or drug combinations; and third, an independent consultant questionnaire concerning the quality of care provided for patients referred to the consultants during the period of the study. Explicit criteria were used in the assessment of indicator conditions and drug utilization, and the primary data source for evaluation of the indicator conditions and drug utilization was the untouched records existing in the primary care practices under assessment. Research assistants did the data extraction and scoring according to the explicit criteria developed.

An indicator condition, as we defined it, could be a disease, a syndrome, presenting symptom complex, or a state such as the prenatal state. The indicator conditions and the drugs studied were selected so as to encompass the entire age and sex distribution and also the types of clinical problems seen in primary health care.

The study focuses primarily on the process of medical practice as suggested by Weinerman (8), Donabedian (9), and Starfield (10).

The use of explicit criteria for quality care appraisal along with the techniques for formulation and application have been presented by Fitzpatrick (11) and Riedel (12). There have been extensive studies on the in-hospital application of medical audit systems and their impact on in-hospital care (13, 14, 15, 16), all of which are dependent on either the need for extensive record review or the development of automated record systems.

Research focused on the primary health care sector, however, is essential. A major study was done on the outpatient clinic of the North Carolina Memorial Hospital at Chapel Hill (17). The Health Insurance Plan (H.I.P.) clinics in New York were also among the pioneers in medical appraisal in non-hospital settings and some of their studies have been enumerated by Densen (18). To a considerable extent criteria rather than performance was the approach taken by Peterson (19), Clute (20), Jungfer and Last (21) in North Carolina, Canada and Australia respectively.

The Tracer Disease concept developed by Kessner and his colleagues (22, 23) has been a significant advance in methodology permitting a purposive and selective sampling

of health care problems to determine quality of care. Further, it has permitted a linkage between process and outcome evaluation.

In spite of the need for further research using outcomes and end-results to appraise health care, we concur with Donabedian (24) that a careful and systematic approach which narrows its terms of reference to process evaluation is valuable, as demonstrated by Lembcke's study (25) in Los Angeles.

The method we outline permits a study of quality of care in primary health care which allows comparison among practices and identification of change over time within a particular practice, using indicator conditions and drug utilization study with explicit criteria as well as an independent consultant evaluation.

The Selection of Indicator Conditions

The following criteria for selecting indicator conditions were used:

1. The condition must be identifiable in general practice.
2. There must be a reasonably agreed-upon approach for management.
3. Where possible, the outcome should be affected by treatment.
4. The condition should occur sufficiently frequently so as to provide adequate data for analysis.

A Peer Advisory Group was established composed of three family physicians highly regarded in the community, each in the 40-50 age group and having been in practice not less than 10 or more than 20 years, representing a four-man, two-man and a solo practice. These physicians were active in "real life" community practices and were not full time academics. The group's function was to select the indicator conditions and drugs, develop explicit criteria for the management of each and then make their own practices available for the pretesting of instruments on patients that they had seen prior to the date they were first informed of the study.

In contrast to the earlier in-hospital medical audit type of study, the primary data source in this study for evaluation of the indicator conditions and drug utilization was the untouched records existing in the primary care practices under assessment. Research assistants (nurses) did the data extraction and scoring according to the explicit criteria developed.

In a study such as this, the identification of the patient, the indicator condition, and the drug being reviewed must remain unknown to the clinician being assessed so as to guarantee the single blind nature of the study. In order to do this, a series of probes were developed which permitted the identification of patients with selected indicator conditions or who received certain drugs during the period of the study.

Five probes were developed. First, each practice kept its day sheet listing the patient's name, complaints, diagnosis, procedure performed, and whether referred. Entries of 43,000 episodes of care were obtained for probing in this fashion. Second, the physicians under study used carbonized, personalized prescription forms exclusively. The carbon copy was retained by the research group permitting them to identify the drugs used. The prescription of certain drugs served as an additional probe to identify an indicator condition, e.g. perphenazine (Trilafon) would reveal a case of depression. The third probe was through the consultants whose records of consecutive consultations performed during the period of the study were reviewed independently. Fourth, the hospital records during the same period were reviewed for the identification of indicator

conditions and drugs. Finally, once the patient's file was entered by any of the above probes, a direct record search of that file was carried out to identify any additional indicator condition. The yield of the various probes is summarized in Table I. In the main study 620 episodes of indicator conditions and 825 episodes of drug utilization were identified by these probes.

Explicit Criteria

The development of explicit criteria proved to be a monumental task. For example, the indicator condition "hypertension" contains 4 categories of severity each having 7 or more criteria for adequate care plus additional requirements for a score of superior. The total document for hypertension fills 10 pages.

The Peer Advisory Group in developing the explicit criteria for the management of depression defined depression for the purpose of this study as an adult patient, 22 years of age and over, presenting with three or more of the following symptoms, (or a stated diagnosis of depression.)

(1) A feeling of depression, (2) fatigue, (3) sleep disturbance and insomnia, (4) apathy or 'turned off' (5) stated nervousness, (6) constipation, (7) loss of libido, (8) loss of appetite, (9) irritability, (10) muscular skeletal discomfort or (11) chronic recurring headache.

Depression was then broken down into three grades.

Grade I Depression without evidence of impaired function or without complications.

Grade II Depression with impairment of function (social, vocational or physical) which has been recognized by one of the following: (a) the patient, (b) a concerned person or relative, or (c) the physician.

Grade III So classified if the patient was suicidal, psychotic or non-functional as determined by one of the following: (a) patient, (b) a significant other, or (c) the physician.

The explicit criteria for the handling of a Grade I depression consisted of the following:

1. A general physical examination done within the past 6 months. If the examination was negative, at least a statement must be entered in the records as "Physical examination negative". If there were positive findings these must be recorded.

2. A medical history, family history, past illness and present complaint.

3. A clear indication of psycho-social enquiry details of the record are not as important as the evidence that the appropriate examination and enquiry has been done.

4. Evidence of psychological support.

5. At least one follow-up visit in a month.

An optional definition of adequate handling of depression would be a consultation or referral to a psychiatrist.

The adequate handling of a Grade II depression was the same as the Grade I plus the fact that there must be evidence of enquiry concerning drugs, either prescribed or self-administered. Treatment by a family physician was permitted up to one month if there was (a) evidence of structured therapy and (b) no deterioration; or up to three months if there was evidence of improvement. Again, a consultation or referral would be accepted as adequate.

The Grade III depression contained the same measures for adequate as have been outlined above plus the proviso that treatment by the family physician for longer than

one month was acceptable if there was evidence of improvement to Grade II. Two options were presented: one was a consultation of referral to a psychiatrist which should be done immediately if there were evidence of suicide, or hospitalization, again immediately if suicide were contemplated.

Finally, for an episode of care to be considered eligible for assessment it must have been managed in full or in part in the ambulatory care setting, it must have fallen within the study period, and there must be evidence that the primary health professional being assessed actually intervened in the management of that episode.

An independent evaluation of quality of care was attempted by the use of a consultant questionnaire containing 10 items concerning the care of each patient referred during the period of the study. Three questions focused on communication between the referring physician, the consultant, and the patient; four related to the appropriateness of the timing, the usefulness, and the clinical value of the referral; two questions dealt with the adequacy of management of the patient by the family physician; and one question attempted to determine the physician's attitude if the referral was requested by the patient or by relatives. Candour in the consultant's response was assured by the use of anonymous code numbers.

Scale for Scoring

An ordinal scale was developed for scoring indicator conditions into superior, adequate or questionable management and for drugs into adequate or questionable. The proportion of adequate or adequate plus superior episodes, out of all episodes scrutinized was calculated.

Scoring for the consultant questionnaire was developed as follows: the responses to each of the 10 questions in the consultant questionnaire were marked on a five-point scale. The responses for each were then assigned to a low, equivocal or high category. Subsequently the proportion of "high", "equivocal" or "low" responses out of all responses in that category was calculated. The resulting absolute scores permitted us to compare one practice with another at a certain point in time, to compare one modality of care with another, or to assess change over time in one practice.

Implementation

The sequence for implementation was as follows: the Peer Advisory Group identified the 11 indicator conditions and 13 drugs or drug combinations, established explicit criteria for management or use of each of the above, designed the consultant questionnaire, and agreed on a scale for scoring. The pre-testing which followed consisted of testing these instruments in the practices of each Peer Advisor on patients seen prior to his first learning of the study. The purpose of the pretest was neither to compare the practices nor to get equal numbers of episodes across the three practices but rather to evaluate the abstracting and questionnaire instrument, test out the strategy, determine the feasibility of deriving scores and to do all this without distorting the practices under study.

In the three Peer Advisory practices the research assistants readily identified 355 indicator conditions, 191 drug utilization episodes and 50 consultant questionnaires. Eleven indicator conditions were tested, 355 episodes assessed and as a result one indi-

cator condition was excluded. The aggregate scores, expressed as a percentage of total episodes scoring adequate and superior, were similar in each of the three practices as would be anticipated by the design of the study. Practice A scored 66 per cent adequate or superior, Practice B 65 per cent and Practice C 61 per cent.

In a similar manner 13 drugs and 50 consultant questionnaires were scored in the pretest. As a result, two drugs were deleted and one added. One question was dropped from the consultant questionnaire, some changes were made in the explicit criteria, and certain refinements in the abstracting methods.

In summary, the Peer Advisory Group felt that the evaluation in their practices was consistent with the performance and that there had been no distortion in the practices during the pretest. Encouraged by this pretest, we applied the methodology to the Burlington Randomized Trial of the Nurse Practitioners.

THE STRUCTURE OF THE BURLINGTON PRACTICE

The basic design of the Burlington trial is summarized in Figure 1 as it applies to the Quality of Care Study. Two practices 'M' and 'N' remained as conventional community practices operating with a traditional family practitioner and office nurse relationship and can be considered for study purposes as one practice, referred to subsequently as the Community Control. They had a combined census of 1,754 families.

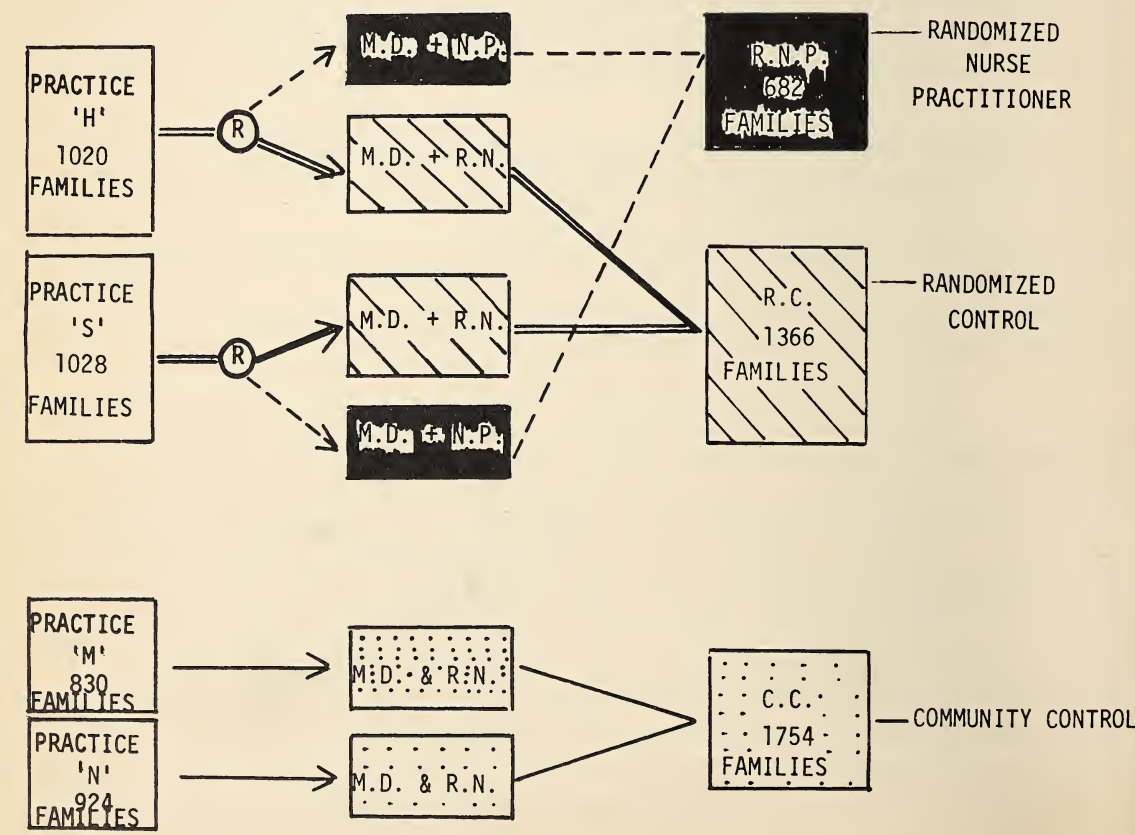


Figure 1. Structure of the Burlington Practice

The two experimental practices of approximately 1,020 families each were randomly allocated two thirds to a family physician and office nurse (cross-hatched area in figure) subsequently called the Randomized Control practice; and one third to the family physician and nurse practitioner group (shown in the shaded area) and referred to as Randomized Nurse Practitioner practice. The abbreviations RNP, RC and CC will now be used for the respective practices.

In the RNP practice all initial patient contact was with the nurse practitioner who either gave care herself, involved the family physician, or referred to a consultant at her own discretion with approximately 70 per cent of episodes of care given exclusively by the nurse practitioner. At the start of this study, patients in the RC and RNP groups were identical as to age, sex and other parameters including satisfaction with the clinical services received. Refusal rates for the random assignments to the RC and RNP groups were only 0.2 per cent and 1 per cent respectively with a subsequent drop-out rate during one year of less than 1 per cent from each group.

The final list of indicator conditions used in the Burlington trial were as follows:

1. Otitis Media
2. Hypertension
3. Prenatal Care
4. Care of the Newborn
5. Immunization
6. Depression
7. Urinary Tract Infection in Females Over 16
8. Knee Injury
9. Pityriasis Rosea
10. Anaemia

TABLE I

PROBES

Probe	Indicator Condition	Drug Utilization
Day Sheet	446	439
Prescription	133	197
Hospital	37	13
Consultation	4	6
Direct Record Search ^a	0	170
TOTAL	620	825

^a Secondary—after probe had given access to file.

Table II demonstrates the number of episodes of indicator conditions evaluated. One hundred and sixty-eight episodes of indicator conditions were identified by the probes in the RNP practice, 223 episodes in the RC and 229 in the CC practice for a total of 620

TABLE II

EPISODES OF INDICATOR
CONDITIONS EVALUATED
IN THREE PRACTICES

Indicator Conditions	RNP	RC	CC	Total
1	39	39	36	114
2	9	12	13	34
3	13	31	23	67
4	17	34	33	84
5	10	11	19	40
6	37	33	34	104
7	24	26	36	86
8	11	16	14	41
9	4	11	11	26
10	4	10	10	24
TOTAL	168	223	229	620

TABLE III

INDICATOR CONDITIONS
BY PRACTICE SCORED
"ADEQUATE OR SUPERIOR"

Indicator Conditions	RNP Episodes	%	RC Episodes	%	CC Episodes	%
1	29/39	74	29/39	74	24/36	67
2	5/9	56	8/12	67	4/13	31
3	10/13	77	22/31	71	16/23	70
4	12/17	71	22/34	64	27/33	82
5	9/10	90	5/11	45	2/19	11
6	30/37	81	31/33	94	24/34	71
7	10/24	42	16/26	62	19/36	53
8	4/11	36	8/16	50	8/14	57
9	4/4	100	8/11	73	6/11	55
10	3/4	75	4/10	40	9/10	90
TOTAL	116/168	69	153/223	69	139/229	61

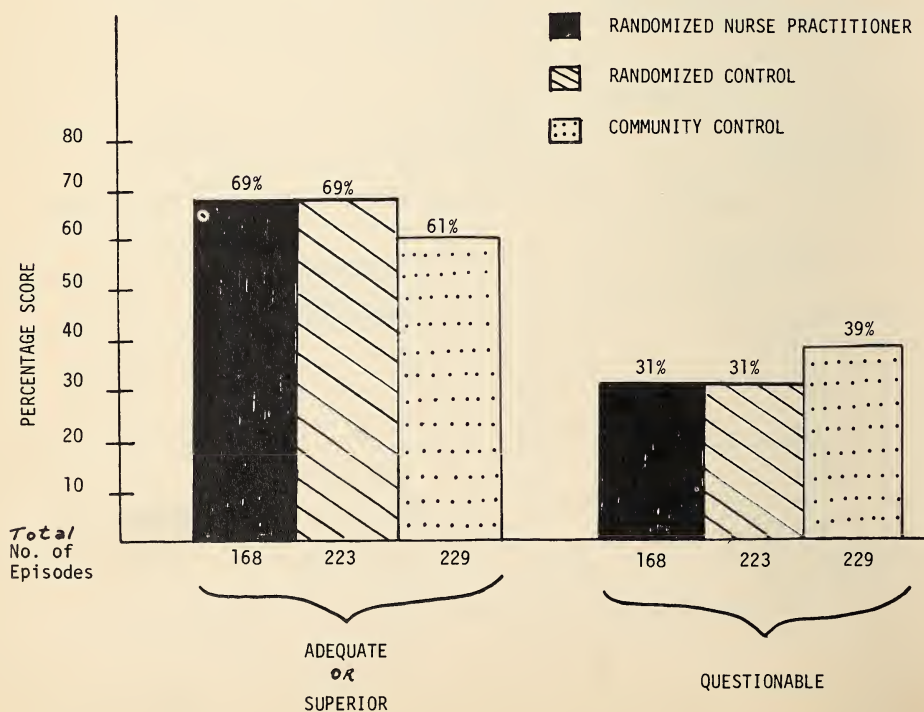


Figure 2. "Aggregate Score" Indicator Conditions by Practice

episodes. The aggregate score for all the indicator conditions across the three practices is summarized in Figure 2. Analysis did demonstrate differences in the proportion of episodes scoring superior across the three practices but for the purpose of this paper we will focus only on the threshold of adequacy, *i.e.* distinguish between scores for at least adequate and for questionable. A more detailed breakdown of the scoring for each indicator condition across the three practices is shown in Table III. Sixty-nine per cent of the episodes of indicator conditions in the RNP practice scored adequate or superior, 69 per cent in the RC practice and 61 per cent in the CC practice. One would stress that the Peer Advisory Group decided that equal weighting would be given to each indicator condition or drug utilization and that each episode, therefore, would have equal value in the final scoring. Examination of the various cells in Table III indicates considerable differences in the percentage of adequacy for various indicator conditions within one practice as, for example, in indicator conditions Nos. 6 and 7 in the RNP practice suggesting that the method is reasonably sensitive.

Drug Utilization

The following drugs were studied in the Burlington Trial:

1. Chloramphenicol
2. Tetracycline
3. Amphetamines
4. Multivitamins
5. Haematinics
6. Phenylbutazone
7. Hypotensive Medication
8. Steroids
9. Vitamin B₁₂
10. Antidepressants
11. Tranquillizers and sedatives
12. Combination of diuretics and cardiac glycosides
13. Antibiotics

The Peer Advisory Group developed the following criteria for permitted use of certain M.M.D. Amphetamines were permitted only if there was an established diagnosis of (1) narcolepsy, (2) idiopathic postural hypertension, and, (3) in children only if there was a) minimal brain damage b) cerebral dysfunction c) functional behavioural problems in a hyperkinetic child.

Antidepressants such as nortriptyline, amitriptyline, thioridazine were permitted only if there was evidence of follow-up visits and concurrent psychotherapeutic support by the family physician or by a consultant. In addition, not more than 50 pills could be prescribed at one time.

The explicit criteria for the prescription of tranquillizers, sedatives and other mood-modifying drugs including barbiturates stated that a short course (a maximum of 2 weeks) was permitted providing there was clear evidence of symptomatic justification, *i.e.* "personal crisis", "death in the family", "transient stress situation". Long term (greater than 2 weeks' supply or a repeat of a short term course for the same condition consecutively) was permitted only if one of the following pertained: a follow-up visit had been arranged, a consultation had been planned, or there was a specific statement justifying long term use "inadequate personality structure", "patient decompensates rapidly in any stress situation", "terminal carcinoma".

Also, there must be evidence that the health professional knows this patient or family well over a significant period of time, *i.e.* not less than 6 months; not more than 50 pills may be prescribed at any one time; and diazepam (Valium) was permitted if it was specifically being used as "a muscle relaxant."

The percentages of all drug episodes by practice scored as adequate or questionable are shown in aggregate form in Figure 3 and in detail by each drug across the three practices in Table IV. As with indicator conditions, the Peer Advisory Group decided that each episode was of equal value. The RNP practice scored 71 per cent adequate, RC 75 per cent and the CC 68 per cent adequate.

TABLE IV

DRUG UTILIZATION BY PRACTICE
SCORED—"ADEQUATE"

Drug Number	R N P		R C		C C	
	Episodes	%	Episodes	%	Episodes	%
1	38/38	100	38/38	100	37/37	100
2	37/38	97	37/38	97	36/37	97
3 ^a	—	—	0/1	0	1/7	14
4	3/3	100	6/7	86	6/7	86
5	12/13	92	22/26	85	24/39	62
6	34/35	97	34/38	89	37/39	95
7	8/15	53	9/15	60	3/32	9
8	12/14	86	18/21	86	28/29	97
9	3/5	60	4/6	67	4/5	80
10 ^b	5/13	38	13/33	39	10/25	40
11 ^c	18/41	44	31/44	70	31/41	76
12	3/7	43	8/12	67	6/15	40
13	25/42	60	31/43	72	27/39	69
TOTAL	160/226	71	213/284	75	213/315	68

^a Amphetamines

^b Antidepressants

^c Tranquillizers and Sedatives

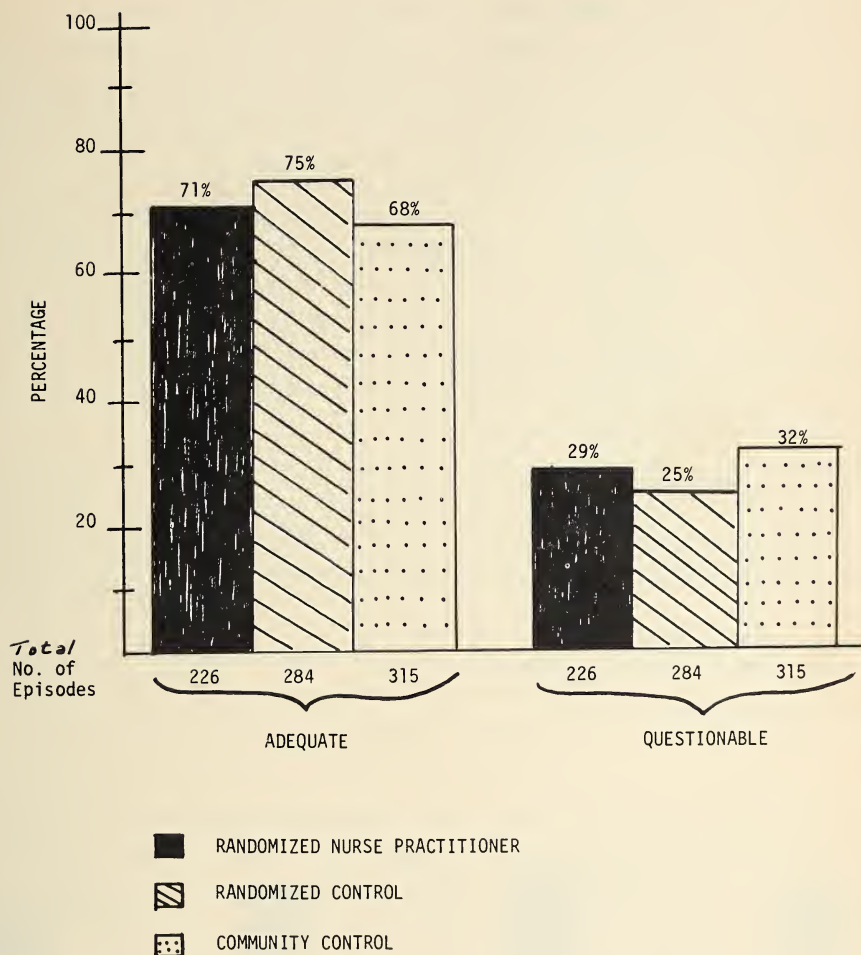


Figure 3. *Drug Utilization by Practice. Aggregate Score*

Three drugs are worthy of mention.

Drug 1 (chloramphenicol) is contraindicated today in primary care, whereas Drug 2 (tetracycline) is an appropriate alternative. To reward a correct decision for the non-use of chloramphenicol it is assumed that a choice between these two was made each time that tetracycline was prescribed. In order to avoid a double weight for a proper choice, the numbers for chloramphenicol are not entered into the Grand Total. Drug 3 (amphetamine) shows a small number of episodes, as we would expect because this drug should rarely be used in primary care. There are considerable variations in scores within practices and within drugs suggesting the method is reasonably sensitive and can elicit differences for particular drugs across various practices and across all drugs within a particular practice.

While this study focuses on explicit criteria for appraisal of drug utilization, data were available which permitted a brief look at the number of M.M.D. prescribed per 100 adult visits, the sex distribution of all adult visits over one year and finally, the number of mood-modifying prescriptions per 100 adult visits by sex. (Table V). These data are based on an analysis of a defined population receiving primary health care from a single source. They were obtained first by an actual count of prescriptions (written or phoned) from the pharmacies in the community and from the carbon copy of the prescriptions retained in the practice and second, from a tabulation of the actual visit by adults recorded in the day sheets in the practice concerned.

TABLE V

	RC & RNP	CC
Female Adult Visits/Year % of Total Visits	74 %	71 %
Male Adult Visits/Year % of Total Adult Visits . .	36 %	29 %
M.M.P. ^a for 100 Adult Visits—All Causes	6.6	19.8
M.M.P. ^a per 100 Adult Visits for Psychological Causes (Female)	71	75
M.M.P. ^a per 100 Adult Visits for Psychological Causes (Male)	91	55

^aM.M.P. = Mood-Modifying Prescriptions

Extensive studies by Parish (26), Parry (2), and Cooperstock (1) in the U.K., the United States and Canada respectively confirmed the high number of prescriptions for M.M.D. issued by physicians annually. The data presented here are not comparable, however, since the method of obtaining the data and the expression of the data are somewhat different.

M.M.D. were prescribed 6.6 times per 100 adult visits for all causes (RNP and RC practices) and 19.8 times per 100 adult visits for all causes in the CC practice. In the RNP and RC practices 16 per cent of all prescriptions were for M.M.D. and in the CC practice 20 per cent were for M.M.D.

The higher incidence of M.M.D. prescribed for women (Cooperstock (4) reported the recipients of 60 per cent of prescriptions written were women) should be considered against the fact that 74 per cent of all visits to the RNP and RC practices were by women and 71 per cent to the CC practice were by women. Furthermore, in the RC and RNP practices there were only 71 mood-modifying prescriptions given to women per 100 adult women visits for psychological reasons compared to 91 prescriptions for men in the same category. In the CC practice there were 75 prescriptions per 100 adult visits for psychological causes (female) whereas 55 mood-modifying prescriptions were given to men per 100 adult visits for psychological causes.

The presentation of data in this manner is simply to confirm the need to assess prescribing practices for M.M.D. against explicit criteria, as there are clearly distinct differences in this sample of two practices.

Consultant Questionnaire

The questions in the consultant questionnaire focused on the four subject areas of communication between the referring physician, the consultant and the patient; the appropriateness, timing and usefulness of the referral; management of the patient prior to the referral; and finally, the referring physician's attitude to referral. In each of the four areas, the RC and RNP practices had 80-90 per cent of the episodes rated in the high category with the CC practice rated in the 60-70 per cent range. The exception was in the appropriateness of the referral in which all three groups scored within the 88-89 per cent range. (Fig. 4) A more detailed breakdown of the 934 questions answered by consultants into the four areas of enquiry is presented in Table VI. The percentage of episodes scored high, equivocal and low in each category is shown across the three practices. Again it is noted that the CC practice scored lower than the RNP or RC practices apart from Category 2 (the appropriateness and usefulness of the referral). Given the design of the study, one would anticipate that the maximum similarity would occur between the RNP and RC practices with any difference being demonstrated in comparison with the CC practice.

Finally, Figure 5 summarizes the adequate or superior scores previously presented for both indicator conditions and drug utilization. The summary demonstrates that the scoring profiles are consistent for the indicator conditions and drug utilization on the one hand and the external evaluation derived from the consultant's questionnaire on the other (Table VI).

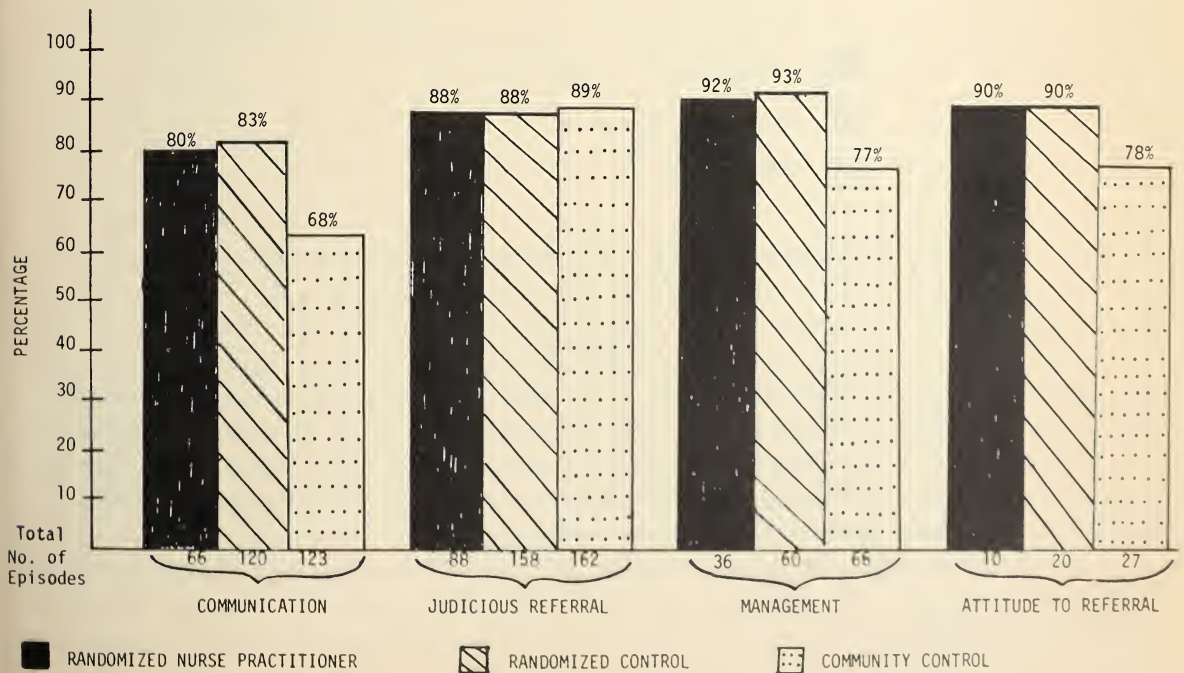


Figure 4. Consultants' Questionnaire by Category. 'High Rating' Aggregate Score.

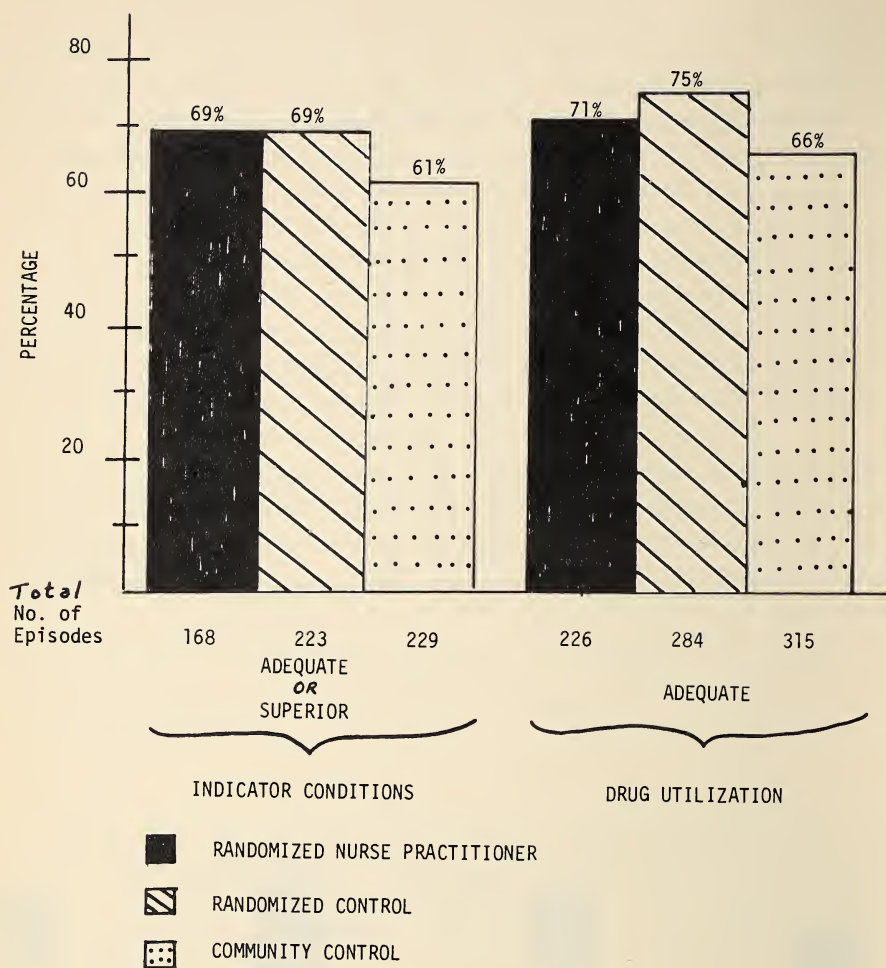


Figure 5. *Indicator Conditions and Drug Utilization. Aggregate Score.*

SUMMARY

The high rate at which M.M.D. are prescribed in the U.K., U.S.A., and Canada has been well documented. Before useful conclusions can be drawn from these data, there is a need to examine critically the prescribing of mood-modifying drugs against pre-determined explicit criteria and to relate this to the assessment of quality of patient care in general in the particular primary health care practices under study.

A method for the evaluation of quality of care in primary care practices has been developed based on the use of indicator conditions and drug utilization with explicit criteria for each established by a Peer Advisory Group of competent and experienced community physicians. In addition, a separate, independent but similar evaluation by means of consultant questionnaires has been developed. A series of simultaneous probes ensured the single blind nature of the study. The primary data source of evaluation was the original

TABLE VI

CONSULTANTS' QUESTIONNAIRE
BY CATEGORY

	RNP		RC		CC	
	Questions	%	Questions	%	Questions	%
Communication						
High	53/66	80	100/120	83	84/123	68
Equivocal	5/66	8	6/120	5	13/123	11
Low	8/66	12	14/120	12	26/123	21
Judicious Referral						
High	77/88	88	139/158	88	144/162	89
Equivocal	10/88	11	16/158	10	12/162	7
Low	1/88	1	3/158	2	6/162	4
Management						
High	33/36	92	56/60	93	51/66	77
Equivocal	1/36	3	4/60	7	11/66	17
Low	2/36	5	—	—	4/66	6
Attitude re Referral						
High	9/10	90	18/20	90	21/27	78
Equivocal	—	—	2/20	10	4/27	15
Low	1/10	10	—	—	2/27	7

practice records. The method appears sensitive, credible and practical. Using this method in the nurse practitioner study, the hypothesis that quality of care would not change as a result of the introduction of the nurse practitioner is confirmed. The validity of the method was indirectly supported by an independent but related end-result study by Sackett (7) done simultaneously on the same population. Mortality, physical function, emotional function and social function outcomes were measured using instruments previously validated and this also confirmed the above hypothesis.

The next series of studies in eight additional Ontario practices is under way designed to test the reproducibility of the method in rural, industrial and additional experimental practices. Reproducibility will also be tested by a co-operative study in one of the Maritime Provinces. A portion of this next series of investigations will validate the results of clinical record searches against direct observation using the same indicator conditions and explicit criteria. Further data will provide a better description of the distribution of the scores for adequacy and may permit us to reach some conclusion about the meaning of absolute scores.

The question of drug dependency was not the primary focus of this study. The methodology presented using explicit criteria for relevant indicator conditions and for the prescription of particular drugs may be a useful model for further research into a possible relationship between the quality of primary health care and the prevalence of drug dependency in a defined population.

ACKNOWLEDGEMENT

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Increasing Alcohol Intake as a Coping Mechanism for Psychic Distress

Hugh J. Parry,¹ Ira H. Cisin, Mitchell B. Balter,
Glen D. Mellinger and Dean I. Manheimer

INTRODUCTION

In a recent paper, Cahalan and Room addressed themselves to problem drinking among American men (1). Their definition of "problem drinking" was an eclectic one. It took in a large number of behavioral aspects (heavy intake, binge drinking) as well as consequences (family problems, job problems).

Our approach in this paper is limited to a single type of deviant behavior: the increased use of alcohol as a coping mechanism for psychic distress. The data involved stem from a nationwide study dealing with the acquisition and use of psychotherapeutic drugs and psychotropic substances conducted in late 1970 and early 1971 by the Social Research Group of The George Washington University and the Institute for Research in Social Behavior of Berkeley, California, with the support and close collaboration of the Psychopharmacology Research Branch, National Institute of Mental Health (2).

Although the bulk of the questionnaire was devoted to psychotherapeutic drugs (e.g., tranquilizers), several items also measured normal² levels of alcohol intake, usual types of beverages consumed and the like, so that each respondent could be classified in terms of his usual drinking level. The classifications used are based on those devised by Cahalan and his colleagues (3).

The psychotherapeutic drug study also examined the coping mechanisms most commonly used by American adults to get through periods of anxiety and/or depression.

¹The Social Research Group, the George Washington University, Washington, D.C.

²By "normal" we mean the amount "usually" consumed at a sitting and the number of days of drinking during the past month.

The coping mechanisms covered a wide range of behaviour such as withdrawal, seeking spiritual guidance, hard work, seeing a physician or psychiatrist. The focus of this paper, however, is on those respondents who stated that they were "very likely" or "somewhat likely" to react to psychic distress by increasing their intake of alcohol above normal patterns.

The precise question wording was:

"Here are some things people tell us they do when they're feeling nervous or upset or a little blue and depressed. As I read each one, tell me whether you are very likely, somewhat likely, or not at all likely to do that when you feel this way."

"Drink more wine, beer or liquor than usual."

There are several broad classes of drug abuse. We can, for example, tentatively classify drug abuse under various headings: use of illicit drugs *per se*; overuse of medically-prescribed drugs (4); acquisition and distribution of prescription drugs through extra-medical channels (5); use of industrial substances (e.g., glue, gasoline) for the purpose of psychotropic effect. Finally, there is the abuse of a psychotropic drug of pleasure and sociability — alcohol — for a medical and psychopharmacological effect: to cope with anxiety and depression.

It is this last use, sometimes overlooked in studies of drug abuse or drinking behavior, with which this paper will deal.

The approach will first be to identify the extent of this problem; next to note the "normal" drinking patterns of those who report themselves as likely to use increased alcohol intake as a coping mechanism for psychic distress. Then differential prevalence rates of coping-mechanism drinking will be examined in terms of demographic characteristics, behavior, beliefs, personality attributes. Finally, a comparison will be made between two groups of heavy drinkers: heavy drinkers who say they use increased alcohol intake as a coping mechanism; and heavy drinkers who say they do *not* use alcohol in this manner.

Extent of the Phenomenon

The national data indicate that about 14 per cent of American adults report a likelihood of resorting to heavier-than-normal drinking when put under conditions of psychic distress. Is this a large proportion or not? Shall we use the alarmist phrase "as many as 14 per cent," or the soothing phrase "no more than 14 per cent"? It is impossible to say. Perhaps the best approach is to cite a few "current" prevalence rates for other psychotherapeutic drugs and psychotropic substances. At least about the same proportion (15%) (6) had used some kind of prescription minor tranquillizer/sedative drug during the year preceding the survey (2). From another source, we find that about the same proportion had tried marijuana (7). About 12 per cent reported current use of over-the-counter psychotherapeutic drugs (2). Six per cent reported acquiring or distributing prescription psychotherapeutic drugs through non-medical channels (5). An insignificant two per cent of American adults reported using more tranquillizers than their prescription directed (4).

"Normal" Drinking Patterns of Coping-Mechanism Drinkers

Before examining the differing patterns of alcohol use as a coping mechanism among various sub-groups in the American adult population, it may be well first to answer one question: what are the "normal" drinking patterns of such persons? Are we dealing with the light and infrequent drinker who increases his intake from one to two drinks in order to combat mild anxiety or depression, or is it a case of a person whose normal drinking pattern can already be classified as "heavy"?

The findings suggest that the person who recognizes in his coping behavior a pattern of taking an extra drink or two to steady his nerves or to lift up his spirits exhibits a "normal" pattern of heavy drinking even when not under stress: two-thirds of such respondents reported regular patterns of drinking which were classified as heavy (or even very heavy), with the pattern most striking among men. (Table I) (Among the larger body of drinkers who do *not* resort to increased alcohol intake as a coping mechanism only about one in four were classified as heavy drinkers.) Clearly, we are not dealing with a typical behavior resorted to only in times of anxiety or depression as much as with an accentuation of normal drinking patterns. In many cases, we suspect, the psychic distress serves as an excuse or justification.

TABLE I

NORMAL DRINKING PATTERNS OF PERSONS REPORTING INCREASED
ALCOHOL USE AS A COPING MECHANISM BY SEX

Normal Drinking Pattern Reported for Past Year	Men %	Women %	All Persons ^a %
Abstainer	* ^b	1	1
Very Infrequent, and Light	6	12	8
Moderate	21	33	25
Heavy and Very Heavy	72	54	66
No Answer	*	—	*
Total	100	100	100
No. of Persons	(219)	(129)	(348)

^a This table is based on all persons reporting such behavior, not on the total sample.

^b The symbol "*" represents less than one half of one per cent; the symbol "—" represents no persons.

NOTE: because of rounding, some Tables will not equal 100 per cent.

Not only do the coping drinkers differ from the non-coping drinkers in respect to usual drinking levels attained but they also differ quite markedly in respect to the type of alcohol usually consumed. The drinkers who used alcohol as a coping mechanism were

predominantly beer drinkers, sometimes in combination with hard liquor and/or wine. The non-coping drinkers were much more likely to favor hard liquor, alone or in combination. (Table II)

TABLE II

USUAL TYPES OF ALCOHOL CONSUMED BY COPING-MECHANISM
DRINKERS AND BY OTHER DRINKERS

Type of Alcohol Usually Consumed	Drinkers Who Use Alcohol as a Coping Mechanism %	Drinkers Who Do NOT Use Alcohol as a Coping Mechanism %
Wine only	2	10
Beer only	42	26
Hard Liquor only	31	42
Wine and Beer	2	2
Wine and Liquor	2	6
Beer and Liquor	11	7
Wine, Beer, and Liquor	9	7
Total	100	100
No. of Drinkers	(344)	(1406)

Demographic Variation

The prevalence of increased alcohol intake as a coping mechanism for anxiety or depression varies markedly among sub-groups in the population. Men, as a group, are twice as likely as women to report such behavior, and in particular young men, aged 18-29 and men living in the Western states. (Tables III and IV) The overall prevalence rates of coping-mechanism drinking for any sub-group in the population would, of course, tend to be a function of the prevalence of any kind of drinking in that group. However, even when we control for this factor by presenting our data in terms of percentages of coping-mechanism drinking among drinkers for each group, the same patterns obtain and in some cases are even accentuated; for example, more than a third of 18-29 year old male drinkers report increased use of alcohol to combat anxiety or depression and over 40 per cent of male drinkers in the West also do so.

TABLE III

PREVALENCE OF COPING-MECHANISM DRINKING BY SEX AND AGE

	Coping-Mechanism ^a Drinking in the Group		Coping-Mechanism ^a Drinking Among Drinkers Only	
Men	N	%	N	%
18-29	241	31	214	35
30-44	282	19	230	23
45-59	308	17	228	23
60-74	218	14	137	22
All men	1049	21	809	27
Women				
18-29	340	10	255	14
30-44	411	11	293	16
45-59	420	8	250	13
60-74	332	3	145	7
All women	1503	9	943	14

^a The first column represents the percentage of coping-mechanism drinking for the whole group; the second column represents the percentage of coping-mechanism drinking among drinkers in the group in Tables III-VIII.

TABLE IV

PREVALENCE OF COPING-MECHANISM DRINKING BY SEX & REGION OF COUNTRY

	Coping-Mechanism Drinking in the Group		Coping-Mechanism Drinking Among Drinkers Only	
Men	N	%	N	%
Northeast	255	20	216	23
North Central	342	18	272	23
South	306	17	197	26
West	146	36	124	41
All men	1049	21	809	27
Women				
Northeast	368	10	286	13
North Central	456	9	289	13
South	473	6	216	14
West	206	12	152	16
All women	1503	9	943	14

Race, education and social class do not appear to be correlated with coping-mechanism drinking. Black drinkers are slightly more likely than whites to report increased alcohol intake under the stress of anxiety and depression; and drinkers from the lowest socioeconomic stratum more likely than those in the highest; but the differences are very small. (Data not shown.)

Religion

As it does in respect to drinking in general, religious behavior and attitudes concerning the importance of religion have an impact on coping-mechanism drinking. Those who consider religion "not at all important" report substantially higher prevalence rates than those who think religion is "very important," whether the rates be calculated on the group as a whole or only among drinkers in the group. (A similar pattern can be found when respondents report their churchgoing patterns.) (Table V) When formal church affiliation is examined, the results are as might be expected: lowest prevalence rates among Jews and members of conservative Protestant denominations and highest among those reporting no religious affiliation, with other religious groups in the middle. (Data not shown.)

TABLE V

PREVALENCE OF COPING-MECHANISM DRINKING BY IMPORTANCE OF
RELIGION TO RESPONDENT AND BY REGULARITY OF CHURCH ATTENDANCE

Importance of Religion to Respondent	Coping-Mechanism Drinking in the Group		Coping-Mechanism Drinking Among Drinkers Only	
	N	%	N	%
Very important	1445	9	859	15
Somewhat important	751	17	592	21
Not very important	240	25	207	28
Not at all important	112	32	92	38
Attendance at Religious Services				
Weekly or more often	1051	7	619	11
Couple of times a month	351	15	253	20
Several times a year	442	16	336	20
Less often than that	682	23	532	30

*Health Patterns and the Increased Use of
Alcohol as a Coping Mechanism*

There seems to be little or no relationship between reported levels of general health and the use of alcohol as a coping mechanism (possibly because the coping drinkers have a disproportionate number of younger respondents among them). There is, however, a connection with the belief that general health has been declining: drinkers who report such a decline over the past five years are slightly but significantly more likely to report using alcohol as a coping mechanism. (Table VI) Nor is the problem simply one of general physical health: among those reporting high symptoms of psychic distress (8), the tendency to use alcohol as a coping mechanism is particularly prevalent. (Table VII) And the same pattern is found among those who report a high level of concrete life crises (e.g., death of a spouse, divorce, job-loss) during the twelve months or so preceding the interview (8). (Table VIII)

TABLE VI

PREVALENCE OF COPING-MECHANISM DRINKING BY OPINION
OF CHANGE IN GENERAL HEALTH

	Coping-Mechanism Drinking in the Group		Coping-Mechanism Drinking Among Drinkers Only	
	N	%	N	%
Health getting better	297	14	210	19
Health remaining the same	1881	13	1318	19
Health getting worse	373	17	224	28

TABLE VII

PREVALENCE OF COPING-MECHANISM DRINKING BY LEVEL OF PSYCHIC DISTRESS

Level of Psychic Distress	Coping-Mechanism Drinking in the Group		Coping-Mechanism Drinking Among Drinkers Only	
	N	%	N	%
None	293	10	181	16
Low	846	11	592	16
Medium	619	13	432	19
High	794	19	547	27

The existing data cannot answer questions about causality: do the psychic distress, life crises, and worsening health contribute to the drinking pattern or is it in the other direction? We suspect, however, that the relationship is circular and self-stimulating.

TABLE VIII

PREVALENCE OF COPING-MECHANISM DRINKING BY LEVEL OF LIFE CRISES

Level of Life Crises	Coping-Mechanism Drinking in the Group		Coping-Mechanism Drinking Among Drinkers Only	
	N	%	N	%
None/Low	647	10	401	16
Medium	1061	12	711	17
High	820	19	631	26

*The Use of Increased Alcohol Intake as a
Coping Mechanism and the Use of Other Psychotropic Substances*

As well as with high levels of psychic distress and life crises, the use of alcohol as a coping mechanism is positively associated with the use of other mood-changing drugs acquired outside the normal medical system of physician visit-prescription-pharmacist. This positive relationship can be noted when it comes to the use of a prescription psychotherapeutic drug acquired through non-medical channels, or a verbal willingness to acquire a prescription drug in this manner, or the use of over-the-counter psychotherapeutic drugs, or the use of marijuana. There is also a definite relationship with heavy smoking. (Table IX) In all of these cases, as in the case of the use of alcohol as a coping mechanism, we are dealing with mood-changing substances acquired outside the normal medical system, drugs which can also be taken when the individual wants to and in the amounts he wants to. The relationship between heavy drinking and marijuana use has frequently been noted (7, 9, 10, 11).

When it comes to respondents who have only used prescription psychotherapeutic drugs acquired through medical channels, however, the association appears to be negative. To some degree, we appear to be dealing with a fairly simple substitution model. Such a relationship is made even more explicit in Table X. Here can be noted the tendency to mutual exclusivity between the use of prescription psychotherapeutic drugs in the past year and the use of increased alcohol as a coping mechanism for anxiety and depression. Young men (18-29) favor alcohol as a coping mechanism, but over the years there is a definite swing to prescription psychotherapeutic drugs. Women, whatever the age-group, opt for prescription psychotherapeutic drugs, and this choice appears to become more widespread with increasing age. But whether men or women, or whatever the age-group, there seems to be little combined usage. Another finding of interest is that, for men and women as a whole, the prevalence of both activities is about equal: the order of one-third of each group makes use of either prescription psychotherapeutic drugs or of alcohol as a coping mechanism, men most often choosing alcohol and women psychotherapeutic drugs (primarily tranquillizers and daytime sedatives).

So far, we have been dealing with a combination of any use of prescription psychotherapeutic drugs versus increased alcohol intake. The comparison can be sharpened when results from different sections of the identical question are compared: how likely are respondents, when they're feeling "nervous or upset or a little blue and depressed" to take a psychotherapeutic drug or to increase the normal alcohol intake or both. The figures (Table XI) are very similar to those presented in the preceding Table and serve to underline the findings.

TABLE IX

PREVALENCE OF COPING-MECHANISM DRINKING AND THE USE OF
PSYCHOTHERAPEUTIC DRUGS AND OTHER
PSYCHOTROPIC SUBSTANCES DURING PAST YEAR

	Coping-Mechanism Drinking in the Group		Coping-Mechanism Drinking Among Drinkers Only	
	N	%	N	%
Used prescription psycho- therapeutic drugs prescribed by physician	579	14	395	20
Did not use	1961	14	1354	20
Used prescription psychotherapeutic drugs acquired from extra- medical channels	65	31	55	37
Did not use	2487	13	1697	19
Expressed verbal willing- ness to use a tranquillizer without prescription	229	24	177	31
Would only use if prescribed	2110	13	1447	18
Used over-the-counter ^a Psychotherapeutic drugs	283	21	220	27
Did not use	2269	13	1532	19
Used Marijuana	77	43	77	43
Did not use	2471	13	1671	19
Smoking Score (Cigarettes)				
Never smoked	1011	6	549	11
Former smokers	561	15	420	19
Smoke 1/2 pack a day or less	362	14	275	19
Smoke a pack a day	413	21	333	27
Smoke 1-1/2 pack a day or more	201	33	174	38

^a Here the relationship is even more marked among men: 38% of all males who had used OTC psychotherapeutic drugs and 44% of all male drinkers who had used OTC psychotherapeutic drugs said they were also likely to use alcohol as a coping mechanism. Among males and male drinkers who had *not* used OTC drugs, only 18% used alcohol as a coping mechanism.

TABLE X

INTERACTION OF COPING-MECHANISM DRINKING AND USE OF MEDICALLY-
ACQUIRED PRESCRIPTION PSYCHOTHERAPEUTIC DRUGS BY SEX AND AGE

	Men				
	Age Group				All Men
	18-29 %	30-44 %	45-59 %	60-74 %	
Used Prescription Drug, but No Coping-Mechanism Drinking	3	8	11	18	10
Used Coping-Mechanism Drinking, but No Prescription Drug	29	15	14	11	17
Used Both	2	4	3	3	3
Used Neither	66	73	72	68	70
Total	100	100	100	100	100
No. of persons	(241)	(282)	(308)	(218)	(1049)
	Women				
	Age Group				All Women
	18-29 %	30-44 %	45-59 %	60-74 %	
Used Prescription Drug, but No Coping-Mechanism Drinking	19	28	29	30	26
Used Coping-Mechanism Drinking, but No Prescription Drug	7	7	6	2	6
Used Both	3	4	2	1	3
Used Neither	71	61	63	67	65
Total	100	100	100	100	100
No. of persons	(340)	(411)	(420)	(337)	(1503)

TABLE XI

INTERACTION OF TWO COPING MECHANISMS BY SEX

Coping Mechanism	Men %	Women %	All Persons %
Psychotherapeutic Drugs but NOT Increased Alcohol Intake	9	19	15
Increased Alcohol Intake but NOT Psychotherapeutic Drugs	16	6	10
Both	4	3	3
Neither	70	73	72
Total	100	100	100
No. of persons	(1049)	(1503)	(2552)

COMPARISON OF TWO GROUPS OF HEAVY DRINKERS

The coping-mechanism drinker has been described in demographic and behavioral terms and has been compared with the ordinary drinker. Such data are valuable but can be sharpened still further by refining the comparisons and controlling for normal drinking level, and comparing two sub-groups in the sample:

1. Those who report normal drinking behavior as heavy or very heavy and who also are likely to increase their drinking to combat mild anxiety and/or depression.

2. Those who report normal drinking behavior as heavy or very heavy but who are not likely to increase their drinking to combat mild anxiety or depression.

Both groups can be classified as heavy drinkers but one is using alcohol as a sort of psychotherapeutic drug or medicine while the other group, with equally high normal alcohol intake, appears to use alcohol for more conventional motives. A comparison of the two heavy-drinking groups in terms of their characteristics — both demographic and psychological — and of their behavior may afford insights on some of the reasons why a heavy drinker becomes a coping-mechanism drinker.

Demographic Comparison

The first thing to be noted when the two heavy-drinker groups are compared is that the heavy drinkers who use alcohol as a coping mechanism are slightly but significantly more likely to be men. Thus not only are men more likely to be heavy drinkers than women are, but they are also more inclined, even when normal drinking levels are controlled, to turn to alcohol as a chosen psychotherapeutic drug for the relief of anxiety and depres-

TABLE XII

SELECTED COMPARISONS OF TWO GROUPS OF HEAVY DRINKERS

	Heavy Drinkers who Increase Alcohol Intake as a Coping- Mechanism ("Copers") N = 228 %	Heavy Drinkers who Do NOT Increase Alcohol Intake as a Coping-Mech- anism ("Non-Copers") N = 345 %	Significant Differences ^a
Sex			
Men	71	62	9
Women	29	38	
	100	100	
Region of U.S.			
Northeast	25	36	11
North Central	29	26	
South	24	25	
West	23	13	10
	100	100	
Index of Social Position^b			
Highest	25	34	9
Second quartile	24	26	
Third quartile	25	27	
Lowest	24	12	12
No answer	1	1	
	100	100	
Beverage Usually Drunk			
Wine only	1	4	15
Beer only	47	32	
Hard liquor only	28	37	
Wine and Beer	1	1	9
Wine and Liquor	2	3	
Beer and Liquor	13	10	
Wine, Beer, Liquor	8	12	
	100	100	

^a All differences listed here and in subsequent tables are significant at the .05 level or better.^b Index of Social Position, combining education and occupation, is based on the standard Hollingshead scoring. We have combined his groups into rough quartiles for the purpose of analysis.

sion. Age-groupings appear to make little difference: heavy drinkers aged 18-29 are not significantly more likely than their elders to be coping drinkers.

Quite large variations can be noted, however, in terms of region of the country. The West provides a disproportionate share of coping heavy drinkers, while the Northeast is over-represented among non-coping heavy drinkers. A similar variation can be noted in terms of socioeconomic levels: among heavy drinkers, the lowest stratum is over-represented among those who use alcohol as a coping mechanism; the highest group is under-represented. This class difference may well account for the fact that beer — drunk more by the lower than the higher groups — is the usual beverage for a plurality of the heavy drinkers who use alcohol as a coping mechanism, while hard liquor leads among the non-coping heavy drinkers. (Table XII)

Church Attendance and Attitude toward Religion

Infrequency of attendance at religious services marks the heavy drinkers who use alcohol as a coping mechanism much more than it does the heavy drinkers who do not fall back on alcohol as a medicine. A majority of the first group attends religious services rarely or never, whereas a plurality of the second group claims to attend services weekly. The same type of difference, though rather smaller, can be found when the question is posed in

TABLE XIII

RELIGIOUS BEHAVIOR AND ATTITUDES OF TWO GROUPS OF HEAVY DRINKERS

	Copers N = 228 %	Non-Copers N = 345 %	Significant Differences
Attendance at Religious Services			
Weekly or more often	16	39	23
Couple of times a month	14	13	
Several times a year	19	15	
Less than that, or never	51	33	18
	100	100	
Importance of Religion			
Very important	35	47	12
Somewhat important	34	36	
Not very important	20	14	13
Not at all important	10	3	
	100	100	

terms of attitudes to religion rather than behavior: the heavy drinkers who do not use alcohol as a coping mechanism are more likely to consider religion as "very important." (Table XIII) The differences are underlined by some additional data not shown in the tables: heavy drinkers who do *not* use alcohol as a nostrum for psychic distress (particularly female respondents) are significantly more likely to seek spiritual guidance when anxious or depressed.

*Coping-Mechanism Drinking and the Use
of Extra-Medical Channels*

In their reactions to psychic distress, the heavy drinkers who use alcohol as a coping mechanism are also likely to seek out various drugs and psychotropic substances available

TABLE XIV

COMPARATIVE USE OF PSYCHOTROPIC SUBSTANCES AND OF
PSYCHOTHERAPEUTIC DRUGS BY TWO GROUPS OF HEAVY DRINKERS

	Copers N = 228 %	Non-Copers N = 345 %	Significant Differences
Smoking Score			
Never smoked	14	25	11
Former smokers	22	23	
Smoke 1/2 pack a day or less	14	16	
Smoke a pack a day	28	25	
Smoke 1-1/2 packs a day or more	21	11	10
	100	100	
Psychotherapeutic Prescription Drugs Outside Medical Channels During Past Year			
Yes	10	2	8
No	90	98	
	100	100	
Marijuana Past Year			
Yes	13	6	7
No	88	94	
	100	100	

outside the normal medical channels to a significantly greater extent than normal heavy drinkers. Thus they are more often heavy smokers as well as heavy drinkers. They are more likely to have used marijuana in the preceding year. They more often report having obtained or dispensed prescription psychotherapeutic drugs without medical sanction. (Table XIV) However, they are not significantly more likely than the normal heavy drinkers to have used a prescription psychotherapeutic drug during the past year. Part of this greater tendency to avoid standard medical channels can be attributed to the higher proportion of men among the group: male respondents in the total sample were considerably less likely than females to report having visited a physician in the year preceding the survey (2). But even among female coping-mechanism drinkers there was also a tendency to avoid the use of formal medical channels.

Levels of Stress

Indication that the coping-mechanism heavy drinking group is, indeed, under a greater amount of stress and objectively suffers from higher levels of psychic distress is evidenced by a considerable number of criteria. They are less likely to feel their health is "excellent"; they are more likely to feel they aren't getting enough out of life; their marriages are more likely to be rated as only "average" (often an evasive answer meaning "unhappy") or not too happy; they are more likely to have problems with their children; they get less satisfaction from their jobs. (Table XV)

The two groups of heavy drinkers were also classified in terms of a shortened version of a well-developed symptom list that has been used in a series of drug evaluation studies with psychiatric clinic outpatients (8, 12). Each respondent was scored on each of four indices: mood anxiety, mood depression, anergia and impaired cognitive functioning. For each index a minimum threshold of "high distress" was established taking into account both number and severity of symptoms reported. Respondents were classified as "high distress" only if they met the threshold on at least two of the four indices, at least one of which had to be anxiety or depression. This classification procedure identified a group of persons who appear to be truly distressed by clinical standards.

A comparison of the two types of heavy drinkers indicates that those who use increased alcohol as a coping mechanism are indeed substantially more likely to be suffering from a combination of symptoms indicative of high levels of emotional distress — in particular from anxiety and/or depression. (Table XVI) Using alcohol as a coping mechanism, then, appears to be associated with real needs, even though such use may often aggravate those needs.

Additional evidence suggests that the heavy drinkers who use alcohol as a psychotherapeutic drug or coping mechanism do indeed suffer more than their share of life crises. In order to measure this factor we modified the instrument developed by Holmes and Rahe and known as the Social Readjustment Rating Scale (13). In our adaptation of the instrument, we reduced the number of original items from 43 to 28, eliminating some of the least severe ones. To be classified as "high" a person had to report a total of 150 life crisis units (7). Thus a single item, death of a spouse, most highly weighted single item on the scale, would not of itself justify a high rating.

TABLE XV

HEALTH AND HAPPINESS ESTIMATES AMONG TWO GROUPS OF HEAVY DRINKERS

Own Rating of Present State of Health	Copers N = 228 %	Non-Copers N = 345 %	Significant Differences
Excellent	44	57	13
Good	43	33	10
Fair	10	9	
Poor	3	1	
	100	100	
How Often Feel You are Not Getting Enough from Life			
Very often, fairly often	19	9	10
Sometimes	40	35	
Never	42	56	14
	100	100	
Happiness of Marriage^a (Married respondents only)			
Very happy, above average	66	81	15
Average, not too happy	34	19	15
	100	100	
Children as a Problem (Respondents with children 6-17 years old only)			
Big problem, somewhat of a problem	40	32	8
No problem	60	68	8
	100	100	
Job Satisfaction (Employed respondents only)			
Very satisfied	44	54	10
Somewhat satisfied	33	29	
Neutral	10	5	11
Somewhat Dissatisfied	6	2	
Very dissatisfied	5	3	
No Answer	1	1	

^a The number of cases for married respondents are 146 and 244 respectively; for respondents with children 6-17 years old only 82 and 137 respectively; for employed respondents only 166 and 266 respectively.

TABLE XVI

LEVELS OF PSYCHIC DISTRESS AND LIFE CRISES
AMONG TWO GROUPS OF HEAVY DRINKERS

Levels of Psychic Distress ^a	Copers N = 228 %	Non-Copers N = 345 %	Significant Differences
None, Low	35	55	20
Medium	22	21	
High (Total)	43	23	20
(Depression)	(8)	(2)	
(Anxiety)	(16)	(10)	
(Both)	(16)	(9)	
(Other)	(4)	(2)	
No Answer	* ^b	1	
	100	100	
Life Crisis Scores ^a			
None, Low	17	22	
Medium	36	43	
High	46	35	11
No Answer	*	1	
	100	100	

^a Cf. the levels for the rest of the population—those who are not heavy drinkers of either sort: 21% were classified as suffering from high levels of Psychic Distress; only 25% high levels of Life Crisis.

^b The symbol * represents less than one half of one per cent.

By this criterion, the heavy drinkers who use increased alcohol intake as a coping mechanism appear to have more actual traumatic experiences and complications in their lives: nearly half of them ranked high on the life-crisis scale compared to about a third of the ordinary heavy drinkers. (Table XVI)

Some of the actual experiences obviously “just happened,” but in other instances, the data (not reported in tabular form) indicate that the respondent brought it upon himself. The pattern was particularly noticeable among males. To cite a few examples of self-sought life crises which the heavy-drinking men who used alcohol as a coping mechanism underwent significantly more frequently than the ordinary heavy-drinking males:

they were more likely to have started cheating on their wives in the year and a half or so preceding the survey; to have undergone a long period of unemployment because of quitting a job; to have been haled into court on a serious offense (and in some cases, jailed). Other life-crises of the happenstance variety significantly more often reported by both men and women were: increased domestic quarrels; undergoing financial losses (usually heavy); separation from close friends. Women among the coping-mechanism group were also more likely to have been seriously ill; to have had a valuable possession lost or stolen; to have been separated for long periods of time from a spouse because of business reasons.

It was this combination of life crises that accounted for the group's much higher proportion falling into the high end of the scale. Not only did more traumatic events come to them but they seemed to have, in many instances, actually sought out trouble and complication — particularly the men in the group.

Other Kinds of Coping Mechanisms

In addition to increased alcohol intake, the questionnaire also listed a score of other types of coping mechanisms for mild anxiety and depression. These included: giving one's self a treat, withdrawal, sleeping, seeking spiritual comfort by prayer or talking with a spiritual adviser, taking a psychotherapeutic drug, physical exercise, or work.

The first thing to be noted is that the heavy drinkers who use alcohol as a coping mechanism are also likely to seek out many other means of coping with psychic distress. A tabulation of coping mechanisms cited by respondents as likely to be used under these circumstances gave the heavy drinkers who use alcohol as a coping mechanism a mean score of 7.70 different mechanisms likely to be tried. The ordinary heavy drinkers' score was only 6.40.

The heavy drinkers who use alcohol to cope with psychic distress, as we have noted above, are more likely to report severe symptoms, to have undergone "real" troubles recently. Increased alcohol intake is merely one of many coping mechanisms they turn to. It is as if they were floundering around trying to find something that would work.

They are substantially more likely than the ordinary heavy drinkers, for example, to try to cope with anxiety and/or depression by giving themselves a treat — new clothing or an expensive dinner; to withdraw — either by avoiding people or sleeping; to suffer passively hoping it will just go away.

Psychological Attributes and Basic Values

Finally, we come to the question: do the heavy drinkers who use alcohol as a coping mechanism appear to differ from the ordinary heavy drinkers in terms of psychological attributes and values? Are there certain aspects of personality, certain belief systems connected with coping-mechanism heavy drinkers which do not apply to the same degree with ordinary heavy drinkers who do not use alcohol overtly as a medicine.

The questionnaire contained a number of short psychological scores covering such concepts as life-satisfaction, stoicism and the like. Additionally, it contained an item on basic life-values.

On the basis of comparison of the two heavy-drinking groups in respect to these personality and belief items, we noted several significant differences. (Table XVII)

TABLE XVII

SOME PSYCHOLOGICAL ATTRIBUTES OF TWO GROUPS OF HEAVY DRINKERS

	Copers N = 228 %	Non-Copers N = 345 %	Significant Differences %
Index of Life Satisfaction			
None, Low	22	11	11
Medium	45	35	10
High	33	53	20
No Answer	—	1	
	100	100	
Index of Sensation-Seeking			
None, Low	10	12	
Medium	47	56	9
High	43	32	11
No Answer	—	1	
	100	100	
Index of Stoicism			
None, Low	23	13	10
Medium	65	72	9
High	11	15	
No Answer	—	1	
	100	100	
Index of Dependency			
None, Low	17	25	8
Medium	42	45	
High	40	29	11
No Answer	—	1	
	100	100	

First of all, the heavy drinkers who used alcohol as a coping mechanism were significantly more dissatisfied with life in general. The finding was hardly unexpected in view of their higher levels of psychic distress and life crisis. Not only are they in fact more likely to have troubles, but they are more likely to be aware of them.

The coping-mechanism heavy drinkers are also more likely than the ordinary heavy drinkers to rank high on dependency. To paraphrase some of the items on the score, they want people to be demonstrative toward them, they bruise easily and pout and act hurt

to achieve sympathy. The group scores lower on stoicism than the ordinary heavy drinkers. Again, to paraphrase some of the items, these drinkers are less likely to believe in keeping a stiff upper lip, in hard work and perseverance under hardship.

The coping-mechanism heavy drinkers have a greater tendency than the ordinary heavy drinkers to value risk and sensation. They are less likely to honor the motto "play it safe"; more of them like to gamble; more of them would like to indulge in exciting experiences to which risk is attached, such as driving a racing car.

Some of the differences above are underlined when we examine the basic life-values of the two groups, the statements that they would like to be able to make in looking back over their lives. The statements were divided into two groups of related life-styles. The first, we called the Emotional-Sensate cluster. It consisted of the statements "I have enjoyed life and had fun"; "I have been loved"; "I have enjoyed the beautiful things in life." The second cluster was the Work-Morality grouping. It consisted of the statements "I have always done my work to the best of my ability"; "I have lived a moral, respectable life"; "I have raised my children to be respectable members of society." (A seventh statement — "I have made a lot of money" — was not included in the analysis.)

The respondents were asked to pick any three statements. If they picked two statements from either the Emotional-Sensate or the Work-Morality clusters, they were assigned to that grouping.

When we compared the two heavy drinking groups, at first we found no significant differences in distribution of basic values. A second-step analysis, controlling for sex, however, indicated that among female heavy drinkers, the ones who used alcohol as a coping mechanism were much more likely to express Emotional-Sensate values (two-thirds of them), while the ordinary heavy drinkers divided evenly. Among male respondents, no significant differences were found. (Table XVIII) (Note: the same total set of comparisons was also made between two similar *non-heavy* drinking groups. The results were found to be in the same direction in most cases, but were often not statistically significant. For this reason, they are not reported.)

TABLE XVIII

BASIC VALUES OF TWO GROUPS OF HEAVY DRINKERS BY SEX

	Copers		Non-Copers		Significant Differences (Women only)
	Men %	Women %	Men %	Women %	
Basic Values					
Emotional-Sensate	50	65	52	50	15
Work-Morality	43	28	42	48	20
Mixed	7	7	6	2	
Total	100	100	100	100	
No. of Persons	(161)	(67)	(207)	(138)	

SUMMARY AND CONCLUSIONS

A recent national survey on the acquisition and use of psychotherapeutic drugs and psychotropic substances by American adults provides data on a special group of drinkers: those who by their own reports are likely to increase their normal intake of alcohol when suffering from anxiety and/or depression, a group who in fact are openly using alcohol as a psychotherapeutic drug, as a coping mechanism for psychic distress.

This group of "coping-mechanism" heavy drinkers amounts to about 14 per cent of American adults. Most of its members in their "normal" drinking patterns can be classified as heavy drinkers. Men, as a group, are twice as likely as women to report such behavior, and particularly men aged 18-29 living in the West. Members of the group are less likely than average to be churchgoers. They are more likely to report high levels of psychic distress and of life-crises. Their use of alcohol as a coping mechanism for psychic distress is particularly associated with higher use-rates of other drugs acquired outside the ordinary medical system: marijuana; over-the-counter psychotherapeutic drugs; prescription psychotherapeutic drugs acquired and dispensed extra-medically.

Taking the sample as a whole, our data suggest a substitution model between increased alcohol intake as a coping mechanism for psychic distress and prescription psychotherapeutic drugs: individuals generally use one or the other in such circumstances.

When "normal" level of alcohol intake is held constant, we find many of the same variations. Heavy drinkers who use alcohol as a coping mechanism are more likely than ordinary heavy drinkers to be male and to live in the West. The age differential, however, is wiped out. A new variation becomes significant: those in the lowest socioeconomic stratum are significantly over-represented among coping-mechanism heavy drinkers. The ordinary heavy drinker is likely to name hard liquor as his normal tipples; the coping-mechanism heavy drinkers more often opt for beer — possibly a reflection of class difference in the two groups.

The differences in church attendance and attitude toward religion referred to earlier also hold up when normal alcohol intake is held constant. So does the greater tendency to seek out drugs and psychotropic substances outside the conventional medical channels.

The comparisons indicate that the coping-mechanism heavy drinkers are, indeed, under more stress than ordinary heavy drinkers: in their general health, marriages, relation to children, job satisfaction. Well over 40 per cent of the group report severe symptoms of emotional distress, and/or a high level of life crises — particularly of the type sought out, e.g., court appearance on a serious charge; cheating on a wife; suffering unemployment because of quitting a job.

Presumably because of the higher level of stress, the coping-mechanism heavy drinkers are more likely than the ordinary heavy drinkers to seek out a larger number of coping mechanisms, as if floundering around trying to find something that will work. The differences are particularly marked in such coping mechanisms for anxiety and depression as: giving oneself a treat; withdrawal — either by avoiding people or by sleeping; suffering passively just hoping it will all go away.

Finally, the coping-mechanism heavy drinkers appear to differ from ordinary heavy drinkers in terms of personality and basic values. They are more likely to be generally disgruntled with life; they are more often dependent, and bruise easily; they are less stoical. At the same time the group appears to contain a high proportion of risk-takers. Females among them are particularly likely to have basic values that can be classified as

Emotional-Sensate rather than Work-Morality oriented. Among males, however, there is no significant difference in this respect between the two groups of heavy drinkers.

Many studies of heavy drinkers have classified them in terms of the amount usually consumed at a sitting and the frequency of occurrence of such sittings. Our data suggest that heavy drinkers as a group can be divided into two additional (and fairly equal-sized) classes. Of the heavy drinkers in our sample, as many as 43 per cent of the males and 33 per cent of the females also could be classified as coping-mechanism drinkers.

APPENDIX

Three Measurements Used in the Paper

In the course of our discussion on the use of increased alcohol intake as a coping mechanism for psychic or emotional distress, we have referred to three different measurements: high consumption of alcohol; high levels of psychic or emotional distress; high levels on the Life Crisis score. All these measurements have been described elsewhere but in order to save the reader the trouble of running down various citations in our paper, we are providing in this appendix descriptions of the three measurements.

A. Measurement of High Consumption of Alcohol. — Respondents were asked whether or not they had used alcohol during the past year and how many drinks they usually had at one sitting. They were also asked on how many days during the month preceding the interview they had used alcohol. On the basis of these data we were able to combine the two factors of frequency of drinking and normal amount consumed, and thus rate each respondent on a scale of drinking behavior.

The scoring was as follows:

Abstainer: no drinks in past year;

Very infrequent: no drinks in past month;

Light: one to three sittings in past month, one or two drinks per sitting;

Moderate: four to 20 plus sittings in past month, but only one or two drinks a sitting; OR one to three sittings with three to four drinks a sitting the usual pattern;

Heavy: four to 20 sittings, with three to four drinks the usual pattern; OR one to 20 sittings with five or more drinks the usual pattern;

Very heavy: 21 or more sittings with either three or four or five or more drinks the usual pattern.

For the purpose of our analysis, the "Heavy" and "Very Heavy" drinkers were combined. A separate analysis of the two groups, however, indicated that the same associations and correlations were to be found for both groups.

In this classification, following Cahalan and his colleagues, we have given more weight to normal number of drinks per sitting than to number of sittings. A respondent who had one or two drinks before dinner regularly each day might consume as many as 60 drinks a month without ever being intoxicated; another who normally drank seven drinks per sitting, but only on Saturday nights, would be intoxicated several times in the month but would in fact have consumed only half as many drinks over that period. Thus the average number of drinks consumed in the month prior to the survey by each of the groups can be misleading. With this caveat in mind, we can give a rough estimate of over-all consumption for each group.

Light drinkers: Mean of three drinks consumed in month preceding the survey.

Moderate drinkers: Mean of 16-17 drinks, rarely more than two at a sitting.

Heavy drinkers: Mean of 35-36 drinks, typically four to seven at a sitting.

Very heavy drinkers: Mean of 88-121 (depending on measurement used), typically many sittings and a large number of drinks at a sitting.

It has been a truism of alcohol research for many years that a shot glass of whiskey (either straight or in a mixed drink), a four ounce glass of wine or a 12 ounce can or bottle of beer contains about the same amount of absolute alcohol per "drink." Thus, most drinkers, whatever their beverage, are getting about the same amount of alcohol per "drink."

B. *Measurement of Levels of Psychic Distress* — Each respondent in the survey was given a list of symptoms previously clinically tested as covering the most commonly reported symptoms of psychic distress. For each symptom, the respondents were asked the following questions: is the symptom a current one (within the past 12 months), did the respondent used to have trouble with the symptom (is it now under control or is it gone), or did the respondent never have the symptom. Furthermore, for those symptoms which are current problems or are under control, we asked how severe the symptom was ("a lot of trouble" or "not much trouble").

On the basis of these data, each respondent was assigned a score for each symptom:

Numeric code	Level of distress
0	None: symptom coded "never" or "gone."
1	Low: symptom present ("yes" or "under control") but not much trouble given respondent.
2	High: symptom present and "a lot of trouble" given respondent.

The symptoms were then grouped into four categories:

Mood Depression: bored, lack of interest, hopelessness, feeling sad, crying without reason; feeling blue or depressed. (four items)

Mood Anxiety: feeling afraid, worrying, nervousness, tenseness, excitement, restlessness, avoiding certain places, people or things because they are frightening. (six items)

Anergia: always tired, inability to get up in the morning and face the day even when getting enough sleep; loss of appetite; trouble in getting going. (four items)

Impaired cognitive functioning: memory loss; inability to make decisions; troubled by unimportant thoughts that keep running through mind. (three items)

High psychic distress level for each respondent was then defined as follows:

Depression: a score of three or more.

Anxiety: a score of four or more

Anergia: a score of three or more.

Impaired cognitive functioning: a score of two or more.

The score on the four classes of items were then combined to form an overall index of psychic distress. To be classified as reporting a "high" level of psychic distress, a respondent had to report high levels for two of the four categories of symptoms, one of which had to be either depression or anxiety.

C. *Measurement of Levels of Life Crises* — Our Life Crisis score is based on that devised by Holmes and Rahe, and later modified and shortened by them from 61 to 43 items. The Holmes-Rahe score consisted of various "events," good and bad, most likely to happen to persons prior to various types of illness and psychic distress (on the basis of respondents' own reports). A group of 394 respondents also scored the gravity of each event — in relationship to marriage as a mid-point. The rough scores were then converted into a 100-point score, ranging from "death of a spouse" (100 points) down to "minor violations of the law" (11 points).

The Holmes-Rahe scoring was extremely effective in predicting later onset of various diseases. Their nomenclature, the Social Readjustment Rating Scale, indicates their homeostatic approach, that is, changes — desirable or undesirable — "do help cause illness."

In our own approach, we made some modifications to the Social Readjustment Scale. Our questions were asked in terms of the 18 months preceding the interview. In particular, we shortened the scale somewhat, since our questionnaire was already long. In

general, when we omitted items, we chose to omit events which were "good," on the surface at least, e.g., "outstanding personal achievement"; "marital reconciliation"; or appeared to be simply some kind of change, with no way of knowing whether it could be listed as "good" or "bad," e.g., "change in recreation."

Additionally, we sub-divided and re-scored some of the Social Readjustment Scale items. A typical example: "pregnancy" was given an original score of 40 points. We used a follow-up item asking whether the pregnancy was desired or not. An undesired pregnancy, we felt, should be weighted somewhat higher than a wanted pregnancy, since to the normal pressures was added the additional one of resentment. Similarly, a change in financial status was put purely in negative terms and scored anywhere from 15 to 57 points depending on the degree of seriousness (small debts to bankruptcy).

The scoring of these modified items was based on the consensus of a panel of social researchers using the scoring of the original Social Readjustment Rating Scale as a jumping-off point, and keeping very close to it generally.

Since our approach was to emphasize negative, unpleasant items as far as possible, we named our version of the score or scale, "The Life Crisis Score."

With the exceptions cited above, nearly all of the items we used were identical to those in the Social Readjustment Rating Scale. It was a case of shortening rather than re-writing. Our scoring, also, was closely comparable. An exception was made in the case of marital difficulties. The original scoring had such items as "arguments with spouse" (35 points); "marital separation" (65 points); "divorce" (73 points). There was also "sex difficulties" (39 points), which in some cases were marital. Thus, it was theoretically possible that an individual could in the course of a couple of years have arguments with a spouse, sexual difficulties, separation and a culminating divorce. The total score would be the rather high score of 212 points. In such infrequent instances, when it was clearly a case of building up to a final crisis, we only scored the single highest crisis (divorce).

In the final scoring, we divided the same into rough thirds:

None/Low Life Crisis —	0-49 points.
Medium —	50-149 points.
High —	150 points or greater.

A respondent could score in the high group only if he had undergone two of the highest-scored crises, one of which had to be "death of a spouse," or a larger number of intermediate or low-scored crises.

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The Role of the Consumer — Compliance or Cooperation?

Jean Jones¹

The primary premise of consumerism is that the consumer must be adequately informed before he can assume a responsible and independent role and act to protect his own best interests. However, becoming adequately informed about psychoactive drugs is a task to challenge the most curious and committed consumer — even though dedicated medical authorities, reformers and educators have all attempted to inform consumers with data they deemed relevant.

In looking at the social aspects of psychoactive drugs, we must first of all define the role of the consumer. The consumer, as recipient of the psychoactive drugs, is recognized as having the central role in the development of problems of drug overuse or misuse and consequently, is inevitably involved in the resolution of these problems. The question then arises as to how active the consumer's involvement is and should be unless he is sufficiently informed about the effects of the drugs prescribed for him.

The complexity of the task of informing consumers of psychotropic drugs is magnified and compounded by the fact that the majority of consumers for whom the drugs are prescribed are in mental hospitals or prisons or are the elderly or children. In other words, the same message, conveyed in the same manner from the same source obviously cannot inform all consumers.

First we might consider the nature of the information on psychotropic drugs that has already been presented to the public.

¹ School of Social Work, McMaster University, Hamilton, Ont., Canada.

Information

Reports. — The Consumers Union Report, *Licit and Illicit Drugs* (1972) alerts us to the dangers of the drastic warning approach through the media. The report shows how the headline treatment used in publicizing the misuse of barbiturates, amphetamines and LSD, instead, popularized 'thrill pills', speed and LSD. The LeDain Commission *Interim Report into the Non Medical Use of Drugs* (1970) also points out the negative effect of the sensational slogan in the propaganda approach. As an example, the Report states that the anti-amphetamine slogan 'Speed Kills' seemed to elicit a response from some youth of trying to test the truth of the slogan by "injecting almost suicidal doses of methamphetamines".

Scare campaigns should not be confused with public information and discussion. Very often such campaigns have merely set up a circular pattern in the following way. Publicizing 'the horrors of the drug menace' has resulted in laws of prohibition. Infractions of these new laws have produced further publicity eventuating in even greater subsequent public curiosity and experimentation.

Both the above reports convincingly demonstrate that neither sweeping generalities nor half truths about drug effects inform consumers or restrain consumer use. On the contrary, they titillate and instigate experimentation, among some segments of the population.

Both reports also emphasize that in drug education the *whole truth* should be told. Since the factual detailed exposition which is essential for informing — not scaring — is incompatible with sensational headlines, it is unlikely to get adequate exposure in the commercial media. Moreover, such voluminous reports as those emanating from the LeDain Commission have limited circulation and readership and thus inform only the small minority of consumers who actively search out information. Both reports also suggest that local authorities seem to have more credibility as sources of information and sponsors of educational programs than remote national agencies. Such agencies are trapped into using the generalized statement and the arresting slogan in the attempt to make an impact on people on a nationwide basis using the same material, in the same format, at the same time. Consumers in Moncton and Vancouver are unlikely to be searching for, or receptive to, the same information at the same time. Consequently, the nationwide program that had relevance for one might well be disregarded by the other.

The LeDain Commission report and the Consumers Union report both suggest that the function of national agencies should be as reliable data resources and co-ordinating centres. The development of the format of informational programs and the delivery of the message on the other hand, must be the responsibility of local groups.

This gives rise to a further troublesome question. Which local groups have the competence as well as the interest, and which should have the responsibility, to undertake informational programs or services in relation to psychoactive drugs? Do the established local agencies directed by professional and leading citizens have the capability of perceptively and accurately reading consumers' informational needs and of developing effective methods of meeting them? Would such agencies be more successful in communicating information by involving consumers from the target groups; in helping design, adapt, even perhaps proposing programs? It should be emphasized that we are raising the question of the potential of consumers in significant numbers to influence decision making and are not giving nodding approval to the token representation of one youth, or one house-bound young mother, or one pensioner on a program sub-committee.

Doctors. — The consumer's own physician could be expected to be the primary source of reliable, relevant and timely information about psychoactive drugs at the time he is prescribing. How competently and responsibly do many physicians meet this expectation? When the physician is prescribing various psychoactive drugs, how routinely does he investigate or even enquire about the other medications the consumer/patient is already taking? How often does he caution him about possible side effects, or the effects on driving competence, or about potential for dependence? The answer, it appears, too frequently is 'not usually'. Consumers can be faulted for passively accepting prescriptions without questioning the physician about its possible limitations or hazards. However, even the activist consumer tends to assume a submissive role as patient. Many consumers are put in a conflicting role on entering the physician's office because they want to actively know what is wrong with them and the plans for therapy, while at the same time they have been socialized to accept a submissive role in the doctor-patient relationship. The consumer's passive compliance excludes any questioning of the double mystique of the physician and the drug. Is not the medical model of the ideal patient still the compliant consumer? Can the physician be expected to convey information which might reduce his position of authority and control in relation to the consumer?

If consumers were to gain confidence in their right and responsibility to question, 'the easy pill' would no longer be the quick, economic, and frequently used method of dealing with "insistent and persistent patients to whom they [the physicians] would otherwise have to allocate more time for a personal visit or a therapeutic interview" as pointed out in the public hearings of the LeDain Commission. The University of Montreal did a pilot survey on physicians' knowledge of the content of the drug combinations they had ordered for their patients. The results indicated that there were serious gaps in the physicians' knowledge of the drugs. This lack of information may be one of the reasons for their reticence in giving full instructions and precise cautions to consumers when they prescribe the drug with the easy-to-remember trade name. Perhaps at a different level, there is as much need for information programs on psychoactive drugs for prescribing physicians, as for the consuming patients.

The message. — The Consumers Union report identifies the misclassification of psychoactive drugs as a basic obstacle in conveying accurate and essential information to consumers. The report contends that the emphasis in classification on licit and illicit drugs is political rather than scientific and misleads the consumers into erroneously associating the 'good' and the less hazardous drugs as licit and the 'bad' and more hazardous with the illicit group. The apparent tolerance on the part of political authorities of such confusion, a tolerance that is reinforced by each sensational propaganda campaign, reduces the credibility of all educational programs. Inconsistencies in approach cloud the factual message.

Surely it is strange that in our society where we have developed careful classification and appropriate cautionary symbols to inform consumers accurately on the relative hazards of household cleaning products, for example, we do not have similar public enlightenment on the relative hazards of tranquilizers, nicotine, marijuana, heroin, barbiturates or alcohol.

Without adequate factual information about psychoactive drugs, the consumer will continue to react, with panic to the headline scares, with apathy to abuses of the 'good' drugs. Consumer organizations can be effective channels of information to consumers through their publications and meetings. At the same time, the support and cooperation of researchers and physicians is essential for a flow of accurate, authoritative and relevant content.

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Perspectives on the New Psychoactive Drug Technology

Henry L. Lennard¹ and Arnold Bernstein

INTRODUCTION

Aldous Huxley, who wrote *Brave New World* in 1932, said that he did not imagine such a world as he pictured would come into existence for hundreds of years. But a number of the forecasts he made have already come true within 40 years, and it seems altogether likely that more will come true within the next twenty.

Under the circumstances there is some urgency for us to assess what has already happened in the field of psychopharmacology and to try to gain some perspective on what is likely to happen in the future; otherwise we will be overtaken by developments in new chemical technologies after they constitute a *fait accompli* when it is too late to do anything about them.

Drugs are used to control disease and to relieve suffering. They can be used in the best interest of people, but they can also be used against them — to manage and to control them. The fearsome quality of many drugs is precisely that they can take over control. Like other technologies, they develop a dynamic of their own. Technologies, as it were, grow and develop according to their own laws, and these are by no means compatible with the requirements of individuals and of society. The automobile, the computer, the pesticide industries, and a host of other new technologies have amply demonstrated this.

The past decade has seen a proliferation of psychoactive chemical agents which have profound physiological as well as psychological effects. They also have far-reaching social

¹Department of Psychiatry, University of California, San Francisco.

consequences. The attention of the public, the press, and the government, however, has been largely preoccupied with the illegal use and distribution of such agents. But drug-taking and drug-giving are part of a much broader problem, and it is the purpose of this paper to direct attention to this broader view.

Since the invention of sulfa drugs around 1940, closely followed by the discovery of the antibacterial properties of penicillin, the world has been tantalized by the notion that chemical agents are man's companions and can produce miracles. The psychoactive drugs designed to alter psychological states and social behavior were also expected to work wonders for individuals and society.

The production of psychoactive agents more than doubled during the ten years preceding 1972. In 1970, physicians wrote 230 million prescriptions for such chemical agents (1). Most prescriptions for psychoactive agents (over 70%) were not written by psychiatrists (2). Coincidentally, during the same period, probably not by chance, the illegal use of drugs also increased year by year.

During 1970 five billion doses of tranquilizers, three billion doses of amphetamines, and five billion doses of barbiturates were produced in the United States (3). It is estimated that about one-third of all Americans between the ages of 18 and 74 have used a psychoactive drug of some type and the percentage continues to increase each year (1, 4). Similar trends are reported in other countries as well (5).

Psychoactive drugs are prescribed for most patients in mental hospitals, for most patients attending outpatient psychiatric facilities, for school children who are behavior problems, for elderly persons in nursing homes, for prisoners in correctional institutions, and for persons who are already addicted to drugs. They are prescribed for "psychiatric" conditions ranging from chronic deteriorated psychoses through psychoneuroses to "nervous" conditions that can only be described as part of the wear and tear of everyday life. They are also prescribed by internists and other physicians for a wide variety of non-specific physical complaints. Each year more and more drugs are used, by more and more people, through both legal and illegal channels, and there is more pressure from more and more sources to increase their use.

This rapid development and exploitation of biochemical technology can hardly be considered an unmixed blessing for humanity. For in the giving and taking of massive quantities of psychoactive agents, a new set of influences and a new modality for social control, both for better and for worse, has been introduced into the lives of individuals, families and the community as a whole, affecting such systems in ways yet to be determined.

Changes in any element of a system necessarily lead to adjustments and changes in other parts of that system. From this point of view, our interest is not simply in drugs, but in social systems and the changes in social systems that bring about, and are brought about by, the use of such psychoactive agents.

Any chemical agent introduced into a body, irrespective of its specific effects, has a range of side effects. The side effects of psychoactive agents are more pervasive and more far-reaching than other biological agents, extending from the person who takes them, to his family and others in his social network, as well as to the community at large. We shall undertake an examination of the role that this new chemical technology has come to assume in our lives and an identification of some of the social forces that encourage the use of drugs to accomplish social and psychological ends, as well as the social outcomes of such use.

Those who are most influential in controlling these usages (physicians, and policy-makers, and to a lesser degree, persons in the populations who are their clients or subjects — children, mental patients, prisoners) are largely unaware of the dangers inherent in this pharmacological approach to what are essentially human and not medical problems.

...If you want nature to treat you well, you must treat nature well. If you start destroying nature, nature will destroy you, and this basic moral precept is fundamental in our present knowledge of ecology and conservation. What we know now about ecology points to the fact that nature exists in the most delicate balance, and that anything which tends to upset the balance will produce consequences of the most unexpected character and often of the most disastrous character.

—Aldous Huxley, 1959 (6)

A WAR OF IDEAS

Contrary to what one might expect, the issues of what should or should not be done in the drug field do not revolve primarily around purely pharmacological or medical considerations. They concern ideas: models, metaphors, meanings, and ways of looking at the problem; not only with the way drugs are to be seen but with the way individuals are seen; with what is social and what is medical; with what kind of behaviour needs to be defined as illness and what kind as socially deviant; with what people are like; and finally, with what one can or should do and to whom, in the name of treatment or medicine or social good.

It would be hard to overestimate the tyranny that ideas exercise over the affairs of man. Ideas affect how a person treats others, as well as how he relates to himself.

It is estimated that 60 per cent of the patients who appear in a general practitioner's office or clinic do so for such nonspecific reasons (7) as loneliness, depression, anxiety, dissatisfaction, or unhappiness. Sometimes they seek help from the doctor because they find it difficult or impossible to measure up to prevalent social prescriptions of what one ought to get out of life. They are not as popular, successful, sweet-smelling, thin, vigorous, or beautiful as they have been led to believe they ought to be and deserve to be. In effect, they are in a physician's office because of the premium placed by our culture on appearance, mood, or performance. It is only too true, as John Corry says, that "there is no end to the ways in which Americans can be manipulated and made to feel that there is something wrong, and that whatever it is, it can be solved by something or someone (8)".

Two sets of ideas are involved here. One is the set of ideals of health, normality and functioning that members of our society are expected to live up to. The second is the notion that failure to live up to these can be remedied through the medium of medical practice, or through drugs taken on one's own initiative.

Medical professionals, indeed everyone working in the social and natural sciences, would do well to re-examine their definitions of illness, their concepts of normality, their notions of what the "real" entities are, the arbitrary boundaries imposed between physical and mental; and to surrender narrow defensive theoretical positions. This point of view leads inevitably to the conclusion that what must be attacked, among other things, is the whole psychiatric intra-personal metaphor. Because they have been either unwilling or unable to transcend the limitations imposed by narrow specialization and by their focus upon isolated units of the system, the media, the professionals and the policy makers have become part of the problem rather than its solution.

Since human beings exist within the network of a social system, we must, in order to assess the role of drug use, apply a systems model, an ecological model. Thus physiology, society and nature must be conceived of as part of a large pattern of interacting systems in delicate balance. One must proceed from the recognition that interventions at any level of the system disturb the balances and the relations among other parts of the system. One needs to examine the "system fallout" from inputs to any part of the system, before one can begin to appreciate the full significance of what one is doing. It is precisely medical intervention at the physiological level without an understanding of the effects upon the whole system that is the problem. It is one thing to expect a physician to assess the physical effects of a given dose of phenothiazine upon a particular person: it is quite another matter to rely upon physicians to assess the social consequences of maintaining 500,000 persons on methadone, another million persons on anti-psychotic drugs and an untold number of other persons on a variety of other potent biochemical agents. Such drugs have major social side-effects. They dampen, sedate, diminish and dehumanize social interaction. Too often they become instruments of social control and management.

The argument advanced by those who see no problem with the widespread prescription and use of psychoactive drugs is that such drugs are prescribed for persons experiencing "psychic distress"; and that since many persons reporting "psychic distress" do not use drugs, then psychoactive drugs are prescribed conservatively by physicians and are underused by the public (8).

If certain human feelings and reactions are defined as psychic distress, and if psychic distress, so defined, is further taken as a symptom or indication of a psychological disturbance, and if psychoactive drugs are the treatment of choice for such disturbances, then indeed, the present use of psychoactive agents is conservative and should be expected to increase.

But psychic distress most often is a condition of human existence. The intensity, quality, and specifics of such distress differ with particular social conditions and circumstances, but human beings incapable of psychic distress would be robots or automatons, devoid of sensibility and responsiveness. Many persons maintained on large doses of the anti-psychotic drugs known as phenothiazines are in fact so characterized, and can only be described as having been "zombified."

Although it is hard to assess the extent, there is hardly any doubt that professionals, through their expansion of psychiatric conceptualization to include anxiety, unhappiness, conflict and tension as symptoms of mental disease, have themselves contributed greatly to the very psychic distress they seek to pacify through drugs. Both mental health professionals and the pharmaceutical industry have, by promoting drug-taking, promoted a model that has contributed significantly to the medicalization and technocratization of human existence.

Ideas about the nature of physical and mental "diseases" have led physicians to practise what can now only be described as the most bizarre forms of "treatments." Moreover, in the name of "treatment," much damage has been done unwittingly to many persons from Benjamin Rush's "terror treatment" (his term, not ours) to lobotomies (9).

Labelling a person as mentally ill has serious consequences in terms of what will be done with him and to him. In this connection it is extremely illuminating to study the account and comments by Thomas Szasz (10) of the first use of electroshock treatment on a human being by an Italian psychiatrist named Ugo Cerletti.

The first human being on whom electroshock was tried was a man, identified only by his initials, "S.E.", by his occupation, "engineer", by the city of his residence, "Milan", and, significantly, by the psychiatric diagnosis attached to him, "schizophrenia."

Although sent to the hospital expressly "for observation", Cerletti used him as an experimental subject for electroshock. Cerletti does not mention having obtained permission for the experiment from anyone. It would appear that having received the prisoner from the police, Cerletti immediately regarded him as his "patient" and himself as the sole judge of the sort of "treatment" his "patient" should have.

This subject was chosen for the first experiment of induced electric convulsions in man. Two large electrodes were applied to the frontoparietal regions, and I decided to start cautiously with a low-intensity current of 80 volts for 0.2 seconds. As soon as the current was introduced, the patient reacted with a jolt and his body muscles stiffened; then he fell back on the bed without loss of consciousness. He started to sing abruptly at the top of his voice, then he quieted down.

Naturally, we who were conducting the experiment were under great emotional strain and felt that we had already taken quite a risk. Nevertheless, it was quite evident to all of us that we have been using too low voltage. It was proposed that we should allow the patient to have some rest and repeat the experiment the next day. All at once, the patient, who evidently had been following our conversation, said clearly and solemnly, without his usual gibberish. 'Not another one! It's deadly!'

I confess that such explicit admonition under such circumstances, and so emphatic and commanding, coming from a person whose enigmatic jargon had until then been very difficult to understand, shook my determination to carry on with the experiment. But it was just this fear of yielding to a superstitious notion that caused me to make up my mind. The electrodes were applied again, and a 110-volt discharge was applied for 0.2 seconds (Cerletti, 1956).

Throughout the experiment, S.E. was treated as a thing or an animal. He had no control whatever over his fate. When, after the first shock, he announced "clearly and solemnly" "Not another one! It's deadly!" his seemingly entirely rational communication had no effect on those who were experimenting on him (10).

The way in which a problem is construed and defined affects the nature of the solutions proposed and the arena within which interventions will take place. For example, if one believes a particular mental disturbance to be organic in nature, one searches within the body for its causes, and undertakes for appropriate medical interventions for its cure. If one believes a mental disturbance to be due to intolerable life circumstances, one looks outside the individual for its causes and undertakes changes in his life-situation for the cure.

Models and theories of treatment and disease have both immediate and long-range consequences for what will happen to the person treated. Some of these consequences are often unintended or unexpected. In this way, models implemented on a large scale to deal with human problems often produce unforeseen social "fallout" of all kinds.

The definition and conception of a human problem is critical in terms of *what* will be done *by* whom and *to* whom. For instance, what one does to treat alcoholism, drug addiction, homosexuality, or mental disturbance — how one allocates time, how one intervenes — is based upon the model one uses to conceptualize the nature of these problems, including how one conceptualizes the boundaries of the theatre of operations and responsibilities.

Virtually all medically-oriented treatment programs are alike in their adherence to an individual disease model which postulates that the causes of a problem and the forces which perpetuate it are located within an individual defined as a patient. Such programs differ only with respect to circumscribed assumptions about the nature of the individual's

"disease" and the specific strategies for effecting therapeutic changes within him. Some treatment programs concentrate on physiological strategies, including chemotherapy, and some stress psychotherapeutic interventions, but in spite of the surface rivalry and debate among adherents of specific techniques, the individual disease model provides a common frame of reference for all of them.

Every form of medical care derives its rationale from theories and models defining illness and treatment. The definition and understanding of a disease usually delineates the boundaries of medical responsibility and concern. Even the individual disease model, with its sole focus upon producing changes within the individual, is sometimes recognized as inadequate within the practice of physical medicine. For example, the responsibility of a physician who diagnoses and treats typhoid fever does not necessarily end after he has rendered medical care to the patient, but may extend to a search for the source of typhoid infection and the protection of those who are in danger of being infected by the patient. Or consider how a physician construes his responsibility to a patient who has diabetes. An important part of his treatment is the explanation of the disease (its hereditary implications, the dangers of infection, circulatory problems, cataracts, and so forth) as well as the control of the disease, (the use of insulin, urine analysis, diet, exercise and so forth). Acting on the basis of this information, a physician will try to help a patient to understand the illness and to change those patterns of everyday behavior which might interfere with its control. As with heart disease, a physician attempts to remain an active force in the life of a patient until he is assured that the patient's way of life has changed in ways which will reduce the dangers from the disease.

In situations such as these it is clearly important to go beyond the effort to produce internal changes in the patient. His membership in certain social systems and his patterns of everyday behavior are often critical in determining the course of his disease, and a conscientious physician will often intervene with members of the patient's family or in other aspects of his life as an integral part of treatment.

Yet in the treatment of mental illness, alcoholism and other drug addictions in which the internal causes, perpetuating forces, and treatment strategies are far less clearly established than those of diabetes, the individual disease model is overwhelmingly influential in determining definitions of the problems and methods of intervention.

Consequences of a Wrong Model

When models of illness and treatment are inaccurate, incomplete, or built upon faulty assumptions, programs based upon them become wasted motion; but the consequences of such programs (the "fallout") may be malignant. Therapeutic undertakings following such inappropriate models become ineffective and wasteful of many resources, both of finances and of personnel. One of the dangers of the social fallout is the generation of pessimism within treatment agencies, funding institutions, and the general public, regarding the possibility of successful treatment. Treatment based on a wrong model results in a fallout that does more harm than if no treatment had been undertaken. Such are the consequences when a patient's condition is diagnosed on the basis of the misapplication of a medical model of disease, and procedures are instituted such as surgery, confinement, or potent medication, which damage the patient even further and endanger his health.

There are other examples of misapplication of the disease model. With almost unbelievable regularity the medical profession, through application of the individual

disease model of human problems, has undertaken to attack and solve social and psychological problems through surgical and chemical means, in spite of an impressive series of disastrous failures ranging over a period of almost two hundred years. (Read Kraepelin's *One Hundred Years of Psychiatry* (11) for a mind-boggling account.) And the end is not in sight. The medical armamentarium of surgical and chemical technologies grows. Ambitious physicians, fascinated with new knowledge about the brain and new technologies of neurosurgery and brain stimulation, are now even offering to solve problems of crime and delinquency.

The conception of heroin addiction as leading to a permanent metabolic defect and a lifelong heroin hunger, provided a basis for Dole and Nyswander to propose methadone as a replacement for opiates (12). The medical model of schizophrenia as being caused by some biochemical imbalance provides a rationale for the use of phenothiazines and other drugs in the treatment of mental disorders. A neurological model of psychoses provided justification for the performance of lobotomies on thousands of persons. On the other hand, a model of schizophrenia such as that proposed by Thomas Szasz (13) or Ronald Laing (14), as reflecting crises in living, while by no means necessarily entirely acceptable, nevertheless leads to far less harmful consequences. At worst it means neglect or undertreatment of some persons, which seems to us vastly preferable to the overkill-overtreatment inherent in the chemical and surgical modalities.

In a recent discussion, Dr. Henry Brill, a former superintendant of Pilgrim State Hospital, asserted that much of what is called "crime in the streets" is, in fact, "pathological aggression" and that "There is a considerable body of experience, and perhaps analogy in experience, with various drugs which would indicate that this does fall within the field of psychopharmacology (15)". In this way are dissension, deviance and delinquency annexed to the province of psychopharmacology.

Medicalization of the Human Condition

The theoretical model responsible for the recruitment of physicians and the deployment of chemical technology in the war against social deviance, crime, misbehavior, alcoholism, mental illness, drug addiction, over-anxiety, over-weight, over-indulgence, over-activity, under-activity, insomnia, over-population, sadness, rage and bizarre ideas, derives from the analogy that these are primarily medical problems and therefore can be solved through medical means.

Once a human problem is identified as a disease, the stage is set for mobilizing the technological apparatus for discovering its cure. There is an increasing inclination to define human problems as medical problems and to medicalize all aspects of human existence. An outstanding example of this attitude is the famous "Midtown Study", an epidemiological study on the state of our mental health. Eighty per cent of the persons interviewed reported feelings and symptoms which the project psychiatrists classified *prima facie* as signs of poor mental health.

The historical development leading to the present monopoly that modern medicine and modern psychiatry exercise over the affairs of the mind is described in an important book entitled *The Manufacture of Madness* by Thomas Szasz (9), and therefore need not be further discussed by us here. Instead, we shall address ourselves to some of those social forces which are at work to maintain or increase the use of drugs as "solutions" for social as well as personal problems.

DEMANDS OF THE SOCIAL SYSTEM

The idea that science and technology have all the answers to our personal and social problems and moreover that the answers are simple and instant is current in our society. For example, a pill against war was seriously proposed recently by a nationally known social scientist (16). Another idea which finds fertile soil in the conditions and problems generated by Western society is that human beings are like machines; that they can be "turned on and off" and can be made to run smoothly.

The metaphor of the body as a machine has profoundly influenced concepts and attitudes toward the human body. Perhaps this more than anything else accounts for otherwise inexplicable medical practices. Machines are essentially passive and static and one operates upon them or repairs them when they are out of order. Machine operators are separate from and qualitatively different from the machines they control. The functioning of a machine is influenced entirely by physical factors; feelings and interpersonal events are not "real" to machines. However, they are to humans.

Mass produced machines are substantially identical and perform in the same way. They and their parts are interchangeable. Each human is unique in respect to his genetic code and history. Human parts are not readily interchangeable as transplant attempts have demonstrated. Human individuals are not interchangeable in relationship networks. Machines are not affected by their histories in the same way that human beings are. Humans are in continuous process of growth and historical development and are, at any given time, largely a product of this complex historical process.

Above all, machines tend to be relatively self-contained. They are not tied into and dependent upon vast social networks for their well-being and survival. The state of one machine does not affect the state of another in the way that the state of one human being affects the state of another. Human beings never exist in isolation from other human beings, and what one does to one human affects many others in significant ways.

Machine technology and automation have allowed many persons more "free time" but society has failed to provide the social forms for the utilization of such time. Technological progress has given rise to the possibility of social justice and economic well-being for all, yet many groups remain disadvantaged and experience their relative deprivation more consciously. Restlessness, the desire for change, hunger for "liberation", a desire for "a sharing in the action", the demand for new social institutions, are apparent and visible among many segments of the community.

Contemporary social systems and institutions — our educational, health, economic and legal institutions — are becoming increasingly obsolete and inadequate to meet the demands being placed upon them, and many persons are becoming increasingly unwilling to accept the limitations of these institutions.

Such social unrest and rebelliousness have created acute and serious problems for these already strained and fragile institutionalized systems. As a result of population increases, industrialization, urbanization, and mobility, the traditional social mechanisms for resolving social problems and dealing with troublesome persons have eroded and are no longer available to provide the means for resolving the rapidly developing crises of living that modern man is subject to. Thus, family, neighborhood and community networks can no longer exert the control, monitoring, and healing functions they once exercised. Other institutions have emerged, but these are cumbersome and costly to develop and maintain.

In the light of these phenomena, the attractiveness of an available scientific technology (*i.e.* psychoactive drugs) that permits control and management of problems created by social conditions can be seen. Moreover, the use of these drugs can be rationalized within the framework of the dominant cultural metaphor: that is, the means are scientific and technological; the problem is medical; and the solution is therapy.

As we have seen, the technology of psychopharmacology is peculiarly functional for maintaining an uneasy and strained social system. Economic forces also contribute to the gathering momentum of this technological development. Actually, billions of dollars a year are being invested in the manufacture, sale and delivery of psychoactive agents and, paradoxically enough, in the development of still other drugs and programs to solve the problems created by their medical and social "side effects". Unfortunately, often the use of drug technology perpetuates malignant social institutions, thereby diminishing the pressure to seek other and more fundamental solutions. We are reminded here of the current attempts in Tokyo to solve the problem of air pollution by means of carrying around individual supplies of oxygen in order to make it possible for people to breathe.

THE GATEKEEPERS

Drugs enter the human population through two gateways; one legal and the other illegal. Although public attention has been focussed on the illegal use of psychoactive agents, by far the larger and more insidious problem relates to legal use of such agents.

With respect to the means by which drugs enter the social body legally, there are again two gateways. Moderately innocuous agents are sold over the counter in drugstores; those more potent and dangerous are prescribed by physicians. Thus, to a great extent, whether or not drugs are introduced into wide use depends upon the gatekeepers — that is, the physicians who stand between drugs and the general public.

Many considerations enter into a physician's decision to administer a potent and toxic drug. Some of these considerations are purely medical in nature. Like the rest of us, physicians are not free agents; they too are subject to constraints emanating from social, legal and organizational sources. They suffer from the absence of other available options for resolving individual distress or social problems; they share the same dominant conceptual models of illness and health, normality and deviance. Finally, they are subject to the same forms of mystification.

As some studies have shown, physician-patient contacts last on the average 14 minutes (17). Two-thirds of these contacts eventuate in the prescription of drugs (one-third of which are psychoactive drugs). Physicians who practise in community mental health clinics see patients for even briefer periods of time, and almost all of their patient contacts result in the infusion of a drug into the patient, and through this route into the community.

Still, it is interesting to note that some physicians, including psychiatrists, manage to resist these pressures. They either refrain from using psychoactive drugs or use them very conservatively, for brief periods, and in the smallest possible therapeutic dosage levels.

Many pediatricians still avoid wholesale application of the diagnosis known as "minimum brain dysfunction", a newly discovered "disorder" which, according to some estimates, afflicts as many as 5 to 10 per cent of all children in the United States (18, 19, 20). Fortunately, some countries, such as Great Britain, have not yet "discovered" the existence of this syndrome in their children, and are lagging far behind us in the use of

drugs for "hyperactive" children (though we suspect that a country that has succeeded in exporting Pepsi-Cola to the Russians will surely not fail to export its latest scientific breakthrough to its oldest ally!).

Physicians are in a uniquely strategic position to limit the flow of drugs into the body social. It is part of the unfolding tragedy that their conceptual model, their training and the contexts in which they practise, all conspire to encourage them to open rather than to close the main gate through which psychoactive agents are infused into the population.

CONSEQUENCES ON GROUP, COMMUNITY AND SOCIAL LEVEL

Within the medical/technological model of drug use, the only effects of psychoactive drugs that have been examined, are on the "symptoms" of the "diseases" of individuals. Almost no information has been gathered on the effects of psychoactive drugs on the interpersonal functioning and social behavior of persons who are "on" such drugs — persons who after all (symptoms notwithstanding) live, love, work, play, make decisions, raise children, and have to continue to conduct their lives while under the influence of drugs. Even less attention has been paid to the consequences for social groups when such drugs are introduced into their midst. In our view these effects are serious, manifold, and worthy of the closest scrutiny. When drugs are given to a middle-aged woman who is upset because her marriage is unhappy or her child is rebelling, or to an elderly person who has been isolated from children and community, or to a child who causes trouble in school, the problem is masked. The drugs decrease the anxiety or unhappiness of the individual and, more importantly, they decrease the amount of trouble his anxiety or unhappiness causes others. It is thus easier for other persons to manage or to cope with the disturbed or disturbing individuals. The drugs do not, however, reach the sources of anxiety or misery — sources which may reside, for example, in an unhappy marriage, in the unfortunate position of the elderly in our society, or in the unsuccessful socialization of many youngsters into group settings. The use of psychoactive drugs as the main avenue of intervention also inhibits the ability of a group to cope with the distress of its members. Drugs lessen a group's ability to develop and enact strategies of human relatedness in response to particular psychological reactions among its members — such as anxiety, grief, rage, or other extreme forms of behavior.

Physicians commonly place individuals who have suffered the loss of a relative through death on heavy sedation (21). True, the sedation enables the individual to enact his social obligations during the funeral and the other ritual occasions, but it deprives him of the full experience of grief which, it is increasingly recognized, fulfills significant psychological functions.

When a family sends one of its members to a physician for a sedative, or when a ward psychiatrist prescribes chlorpromazine for an agitated in-patient, both, in effect, render it unnecessary for respondents in the immediate social environment (the medical and nursing staff) to alter themselves and the pattern of their relationships to deal with extreme or deviant behavior. Drugs alter this basic human function in any group into which they are introduced — families, classrooms, work groups, hospital wards. Moreover, drugs undermine truly therapeutic functions, and the management function is delegated to the drugs rather than to significant parties in the interpersonal environment.

By virtue of their action, psychoactive drugs alter the quality of an individual's relations to the world and to his own body. They impair his capacity to feel and to perceive. They alter the clarity and capacity of all sensory modalities, including taste, touch, sight, sound and smell. Moreover, they diminish an individual's capacity to feel and control his own body, especially denying him access to sensual and sexual feelings. The interference with many of these normal functions often has profound psychological repercussions. To the extent that drugs dull the senses, sedate, numb and immobilize, they de-differentiate human experience and behavior. They make persons more homogeneous by restricting variability in sensation and experience; yet it is precisely for this property that many psychoactive drugs are prescribed. Surely it is a matter of personal preference as to whether one should elect to live a life in which sensation and experience are dulled or exaggerated, or a life in which one's sense of intimacy and relatedness is lost or intensified.

Drugs tend to make things easier for the giver as well as the user. For the giver, the use of drugs diminishes the strain of having to accommodate to difference and deviance in others; the user too is relieved of the burden of adjusting to interpersonal differences since he tends to interact in the "same modality" as other users of the same drug, without effort.

Moving from small social systems (families, classrooms, wards, nursing homes) to the community at large, one can identify a number of potential consequences and hazards posed by the new psychoactive drug technology. Increasing public commitment to the development and employment of drug technology implies a model of human behavior and behavioral change that in itself generates further use of the very drugs (like heroin) which are disapproved of by the scientific and medical community.

The potential for the misuse of psychoactive agents is considerable, especially in relation to problems of social control, and particularly the control of such relatively powerless groups as the elderly, the very young, mental patients, and prison populations. While the use of drugs does not appear, on the face of it, as a naked use of force, that is the general effect achieved, since it immobilizes the users and deprives them (and the community) of many of the options drug-free persons exercise.

Finally, the very existence of a drug technology detracts from a social investment in other options. If children can be controlled through drugs, the expensive task of rebuilding and reorganizing educational structures can be avoided; if addicts can be appeased through methadone there is no need to direct resources and energy to the difficult and costly task of rebuilding their human connections through drug-free communities.

If the symptoms and problems created by human and social injustice are hidden through the use of drugs, our very sense of justice itself becomes blunted.

IMPLICATIONS FOR PUBLIC POLICY

The situation where large quantities of toxic chemical agents are being introduced into the population with encouragement and support of a complex of social forces, economic interests, and public policies, gives rise to serious questions of a moral and social nature.

Decisions about the distribution and use of drugs that affect the very structure of society itself are made by small, highly specialized groups such as physicians, the drug industry, public agencies, and the media. These groups are motivated as much by considerations of self-interest as by concern for the future of society and the best interests of

the community. Moreover, their very nature tends to limit their competence to apprehend the full implications of their decisions and to appreciate the costs of drug use at the interpersonal, social and ecological levels. Physicians are locked into a narrow medical or psychiatric metaphor. The pharmaceutical industry is almost totally occupied by a focus on the development, distribution, and manufacture of drugs. Public agencies are overwhelmed by law enforcement problems relative to drug-associated crimes and the illegal importation and distribution of drugs. And the mass media are busy exploiting the drama of drug miracles and drug horrors. Decisions relating to the application of drug technology to human affairs give rise to issues and consequences of too great importance to be left entirely in the hands of such groups.

In our view, a high priority must be assigned to the immediate public and professional consideration of a number of critical questions that the new drug technology raises. Public discussion should include, at the very least, a consideration of the moral, philosophical, historical and political implications of drug use. Policies and decisions must derive from these considerations rather than from merely traditional medical considerations. Policies on drug giving and taking need to be responsive to the wishes of those most directly affected, *i.e.*, persons defined as patients, and their families.

Who should decide on public policy regarding which psychoactive drugs should be administered — by whom, to whom, and toward what end? In the light of the serious issues raised in this paper, we believe that a re-delegation of responsibility for decision-making is long overdue. For example, should psychoactive drugs be administered only with the consent of those to whom they are given? The larger question is, under what circumstances and for what purposes should drugs be administered without consent? What information about psychoactive drugs should be disseminated in order that informed decisions can be made by patients, families, professionals, and the public? Should all of the available information about the side effects and risks be made public? What social forces and what institutions encourage or discourage the investigation and dissemination of information about drugs?

What kinds of research on long-range consequences of psychoactive drugs (at both the individual and social levels) should be encouraged — and who should have the responsibility to chart and support this research? Federal agencies? The drug industry? University centers? Within whose province does the exposure of the long-range consequences of expedient short-term “solutions”, such as methadone maintenance treatment, fall?

Finally, there is a need to identify more precisely the forces and interests that exert pressure for increased psychoactive drug use, and the mechanisms (many of them covert and not publicly visible) through which this influence is exerted. Guidelines to distinguish between what may be proper influence and what must be rejected as improper influence, are desperately overdue.

TARDIVE DYSKINESIA: AN ILLUSTRATION

As long as we were aware of only a narrow segment of what now turns out to be a complex system of mutually contingent and constraining elements, certain policy questions could not be raised. But as we become aware of the whole spectrum of influences and outcomes of the new drug technology, such neglect is no longer conceptually, morally, or socially defensible.

The wholesale adoption of the use of phenothiazines in the treatment and management of the "mentally ill" provides us with a recent example of the tragic consequences that can follow upon the application of the traditional medical approach — a tragedy which touches upon every one of the policy questions alluded to above.

Even during the early period of enthusiasm over the application of drugs to the management of psychological disturbances, many clinicians were concerned about the possibility that psycho-active drugs might have long-range effects on the central nervous system. But any expressions of caution went largely unheeded, and the primary approach to managing severely disturbed patients was shifted to psychoactive drug "treatment". For a time, it was believed that such side effects as were noticed would subside after the discontinuance of drugs or through administration of other drugs. This view must now be revised. The majority of mental patients in this country are being maintained on drugs, and with the passage of time the long-term effects of the administration of psychoactive drugs are becoming increasingly visible.

A workshop sponsored by the Psychopharmacology Research Branch of the National Institute of Mental Health was called together in 1968 to discuss a new syndrome — referred to as *Tardive Dyskinesia*, which can be recognized in an increasing number of hospitalized mental patients who have been maintained on certain classes of psychotropic drugs over long periods. Tardive dyskinesia is a central nervous system disorder, perhaps with irreversible effects. Its manifestations include involuntary movements, especially affecting the lips and tongue, hands and fingers, and body posture. Consequently, speech may be seriously affected, the face may become distorted and subject to uncontrolled expressions, and sustained normal posture may become impossible. Aside from the physical limitations this damage imposes upon a patient, the carry-over to his potential as a human interactor is also serious. Thus, the dysfunction is twofold: neurological and interpersonal. The chairman concluded the workshop meeting with these remarks:

During the last fifteen years, drugs have been given to a large portion of psychiatric patients with little thought of what the risks are. The films of this workshop have shown a number of fairly severe cases of dyskinesia. But many such cases can be seen if one takes the trouble of walking through the wards of mental hospitals. I feel that we should revise our therapeutic approach with drugs as the risk seems to be considerable. Twenty to twenty-five per cent of the patients are afflicted by this disorder according to our observations; the disorder may last for many years or perhaps indefinitely in the more severe cases. Even if symptoms persist only for months or a few years in the milder cases, the problem still is of considerable clinical importance. (22)

Though reports on tardive dyskinesia have been accumulating since the early 1960s and many hundreds of cases described by 1967 (especially by investigators in Western Europe), psychiatrists were slow to acknowledge its existence. Others went on record as saying that the condition was exceedingly rare. Most of those charged with the care of mental patients presumably either did not recognize the disorder, confused its signs with other drug-induced but reversible neurological conditions (e.g., parkinsonism), or attributed the emergence of stereotyped or bizarre movements to the patient's "mental illness". Many were not aware of the condition or ignored it completely.

For five years, a number of investigators, foremost among them George Crane, placed themselves in the unpopular position of calling this syndrome to the attention of the medical profession, the drug industry, and the government agencies charged with the

protection of the consumer. But it was not until 1972, subsequent to having settled a lawsuit for damages brought by a patient with tardive dyskinesia, that a major drug manufacturer felt it necessary to include a detailed description of this condition in the labelling of phenothiazines, the class of drugs mainly implicated in the development of this disorder.

This fascinating and tragic illustration raises many issues of public policy. What combination of vested interests, forces, ideological blindness and wishful thinking, conspired to keep this problem out of our awareness and "under wraps"? Where was the leadership from those scientists charged with protecting the public interest in the area of psychoactive drugs? How did they justify then, and how do they justify now, their failure to act or publicly acknowledge the toxic hazards of these drugs?

At this time the issues posed by the iatrogenic condition known as tardive dyskinesia can no longer be ignored. There are now many thousands, if not tens of thousands, of patients with symptoms of tardive dyskinesia, who exhibit slight to serious disfigurement and disabilities. Most of the patients are elderly; the majority are either in state hospitals or in the community, receiving drugs from community mental health centers.

As psychiatrists and others become more aware of tardive dyskinesia through belated acknowledgment by the drug industry and the published efforts of a few stubborn professionals, they will be able to recognize its signs in more and more patients. The first issue they must then face is whether or not a patient and his family are to be told that drugs administered to help the patient have resulted in possibly irreversible neurological damage. While it is clear to us that the patient and his family must eventually be told about the effects of the drug, it is also clear that this is not yet being done.

We have heard discussions in which dissemination of information about tardive dyskinesia to patients' families was opposed on the grounds that it might decrease the employment of neuroleptic agents (held to be important tools in the treatment of mental illness) because it would tend to make physicians more conservative about the use of these agents! Surely such a position is both unethical and, at this juncture, unwise. Quite possibly some patients or their families may undertake unpleasant legal actions against physicians, hospitals, and drug companies, once they learn that they have been misinformed. The outcome of such legal actions is unpredictable since treatment can be rationalized on the basis of accepted medical practice undertaken in the best interest of the patient and with good intent, weighing risk and benefit. It is only the professional's resistance to recognizing the condition and his procrastination in acting responsibly that may cast doubt on both his competence and his concern for his patient.

Once it is agreed that the prolonged administration of a potent psychoactive agent poses a serious risk to a patient, a weighing of risks against benefits becomes mandatory. But who should do the weighing? Should it be the task only of the professionals directly engaged in the patient's care, who are for the most part deeply committed to drug treatment and working within medical and mental health organizations, (systems which often do not allow for different strategies)?

A number of strategies have been recommended to minimize the risk of tardive dyskinesia. All of them are sensible and long overdue. They include discontinuing the administration of phenothiazines to perhaps half of the patients now maintained on them, suspending medication periodically for others, and lowering the maintenance doses for still others.

Even such conservative suggestions are not likely to be heeded because of the psychiatrists' fear that some patients will relapse (in terms of the psychiatric criteria

employed), and some will become more troublesome, creating additional work for hospital staffs. Paradoxically, therefore, policy making should not be left entirely to those too closely involved in the giving of drugs, but rather to persons outside the system who could represent the interests of patients as well and who could bring to bear other perspectives. Such outsiders would be less constrained to maintain the status quo.

Finally, with the emergence of tardive dyskinesia, another unforeseen but nonetheless disastrous effect must be added to the long list of drug-induced conditions. Surely one must raise the issue as to whether drug treatments should remain the main avenue of treatment for even the most severely disturbed and disabled mental patients. As Crane puts it:

Clinicians feel that the massive use of drugs is necessary because responders cannot be differentiated clinically from non-responders. Nor is it possible to predict when a relapse will occur in a well-compensated individual. This practice would be justified if neuroleptics were low toxicity agents. While a single dose of any neuroleptic is seldom dangerous, the administration over a period of weeks or months causes a variety of side effects and complications. Parkinsonism, acute dystonia, akathisia, hypotension, drowsiness, leukopenia, jaundice, galactorrhea, photosensitivity, excessive weight gain occur with a certain frequency, but are generally reversible upon drug withdrawal. The only lethal effect is agranulocytosis, usually due to chlorpromazine. It seems to be a rare complication, most likely to occur in the elderly during the first few months of therapy. . . More disturbing was the discovery of changes in the electrocardiograms, particularly in subjects taking thioridazine. This discovery was followed by the report of serious cardiac complications, and the possibility of sudden death. . .

The variety and number of side effects would suggest a certain caution and selectivity in the use of neuroleptics. (23).

We certainly do not underestimate the very considerable problems that will be engendered by abandoning the prevailing drug strategy, especially for groups of disturbed, disturbing, and disabled individuals, (and of course for physicians, hospitals, staffs and social agencies). We envision that it will become necessary to consider seriously the development of a network of new arrangements and more imaginative strategies: for example, residential centers, halfway houses and other protected settings, well-staffed with professionals and non-professionals, that can offer social and human support.

Of course, drug use offers a simpler, more efficient and less costly way of managing large groups of disturbing persons, but it now appears that this strategy has become self-limiting, self-perpetuating, and highly destructive. Heavy reliance upon the drug "solution" has already eroded support for many other possibilities which exact considerably lower social and human costs. These other options must now be reconsidered.

We have described the belated identification of tardive dyskinesia and the belated recognition by the profession of the destructive effects of neuroleptic agents, because its appearance so well illustrates the many elements of the complex system involved in the application of the new biochemical technology to human problems. Tardive dyskinesia is only one example of many. The new drug technology is a hydra-like creature: get rid of one of its rapidly growing excrescences and others take its place. Consider only the potential growth in the use of psychoactive drugs for children, the rapid acceleration of interest in the use of methadone and narcotic antagonists for persons already addicted to drugs, or the use of intravenous Valium and Demerol now being promoted as a routine dental procedure in such scientifically sophisticated areas of the country as Southern California.

We have been accused of being alarmists who do not sufficiently appreciate the benefits of scientific progress and overestimate its darker side. But shall we agree with Archie Jumper, philosopher and acrobat, a character in a play by Tom Stoppard, who allays our fears thus?

Do not despair — many are happy much of the time; more eat than starve, more are healthy than sick, more curable than dying; not so many dying as dead; and one of the thieves was saved. Hell's bells and all's well — half the world is at peace with itself, and so is the other half; vast areas are unpolluted; millions of children grow up without suffering privation, and millions, while deprived, grow up without suffering cruelties, and millions, while deprived and cruelly treated, none the less grow up. (24).

Notwithstanding all of its indisputable benefits, modern technology is changing life on earth in ways not yet even remotely perceived by the architects of that technology. In all phases of modern life, man now is faced with problems created by the remoteness of his actions from their visible consequences. Thus actions such as high altitude bombing, or the dumping of poisonous wastes into rivers and lakes became possible.

While most of us sometimes lose sleep over troublesome but minor personal matters, few of us lose sleep over major public cataclysms such as the bombing of Hiroshima. It is clearly time to begin to lose some sleep over the increasing acceptance of technological solutions and of anti-humanistic models of human behavior. The best prescription may still be \mathbb{R} Humanity.

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Reflecting on Directions in Psychotropic Drug Research

Irving Kenneth Zola¹

In reading these papers I was struck by how they intertwine, how they mutually reinforce each other. At the same time they stand both as independent statements and reports of works in progress. In my remarks I will try to grasp the general tone and direction of this conference and reflect upon it.

We can begin with a generalization about psychotropic drug use. There seems to be general agreement that psychotropic drug use is on the increase although the estimates of its full extent vary. While some shift has been noted in the type of drug use and while even some drugs such as amphetamines have undergone a marked decline, the metaphor drawn by Parish seems an uncomfortably accurate one.

Man appears to require a pharmacological pillow on which to rest his consciousness and this pillow increases in size each year receiving its inflation from many sources, not the least of which is the medical profession. Its overall and increasing size is unaffected by restrictions which are periodically applied to the use of various drugs. These merely result in changes of preference.

The question then immediately joined is what are the reasons for this ever growing use. The answer is clearly a multi-faceted one. Obvious to all is a greater public attention to psychological problems. There is a popularization of a mental health rhetoric reflected in an increasing tendency to define many "problems of daily living" in psychomedical terms. Medical treatment, particularly the use of drugs, seems thus to follow naturally as the appropriate response to such problems. Nothing in this life is, however, as 'natural' as

¹Department of Sociology, Brandeis University, Waltham, Mass. 02154 U.S.A.

one might like to think it. And thus the roles of the pharmaceutical industry and the physician were attended to as important factors in defining drugs as 'appropriate responses.' In terms of the former, several participants pointed out that the industry was not only creating new chemical comforts but also seemed in their advertisements to create new syndromes for which their ministrations were then deemed appropriate. To be sure, their advertisements might contain cautions that drugs were not the only solution to problems of loneliness, alienation, depression, purposelessness, or sleeplessness. The other 'solutions,' however, often required more skill or time than the individual physician possessed and thus the offer of some 'therapeutic' intervention at least allowed the 'physician on the firing line' to do something. It is here that the physician himself seems trapped. On the one hand, he is being trained to be more aware of the psychosocial needs of his patients and psychosocial factors impinging on almost every facet of his medical practice from prevention to rehabilitation. At the same time, he finds himself lacking in the basic knowledge or skills to deal with these issues but is nevertheless pressed by his clinical perspective to do something. Regarding the greater public acceptance of 'psychological ills' it is important to note that members of the public are not merely passive agents. They too read medical advertisements and are impressed by the wonders of medical science and technology and thus when they take their problem to a doctor they expect if not demand of him 'to do something.'

The above set of factors deserves more comment. It is not accidental that the perspectives of the drug industry, the medical profession, and the public feed into one another. For they are part and parcel of a series of value orientations or cultural priorities, characteristic of Western culture in general and the United States in particular. First there is an orientation of man over nature including his own nature and biology. Thus there is no river that cannot be tamed, no mountain that cannot be levelled, no force of nature that cannot be harnessed, and no disease or symptom that cannot be cured or at least treated. This is coupled with our decided preference for action over inaction. This is so dominant a part of middle-class America that on one famous psychological test, an item diagnostic of neuroticism was agreement with the statement that the appropriate thing to be done when confronted by trouble was to do nothing. Put together, these two orientations mean that we believe for every problem there is a solution, and that the solution requires action and activity. The final orientation in our trilogy is one of time — the time required for our action. For us it is the faster the better. Where else but in this culture could a television set that would guarantee a 30 second quicker 'focusing' than its competitors be a major selling point. There is an interesting story about Jean Piaget which is germane. After addressing a group of social scientists about the stages of moral development in children, he turned to the audience for discussion. The first questioner opened, "Well, Professor Piaget, since we know how this is accomplished, can you please tell us how we can speed up the process?" To this Piaget quipped, "Ah, so now we come to the American question." This time-speed perspective seems related to many of our concerns as well as lack of concerns with drugs. Thus the emphasis on speed seems related to our overconcern with 'release time' (the more quickly drugs can get to the 'cough-control center' or dissolve in the stomach) as well as our lack of concern with future consequence of drugs (e.g. a focus on its current use at the expense of careful study of its cumulative effect on persons as well as future generations). Together these three orientations involving 'solvability', 'action', and 'speed' color and support not only what industries produce but what doctors prescribe and what patients expect.

Such an analysis tells us something about the volume and nature of drug use but

little about the actual dynamics and context of that use. Our first focus is on the context. Put most generally, to try to understand, let alone create policies to control, 'psychotropic' drugs in isolation from the understanding of other patterns of medicaments and coping mechanisms is of limited benefit. Let me cite several beginnings made at this conference.

1. In the light of what we are continually learning about mind-affecting substances, it seems shortsighted to over-focus on prescribed medicines to the neglect of other drug-like substances which people use in their daily life including nicotine, caffeine, alcohol and any other over-the-counter drugs. Not only should we learn the extent of such use but the why of it — particularly where a choice is possible for the 'user.' Aside from the fact that this may lead to the understanding of certain chemical interactive effects, it may also shed light on the substitutability or cumulative effects of these 'drugs' on each other.

2. We must also be aware of those drugs which while not being 'psychotropic' in and of themselves do have such side-effects (e.g. antihistamines which also sedate). There is evidence albeit anecdotal, that some prescribing is made precisely because of that side-effect.

3. This issue must also be looked at from the point of view of the consumer. For psychotropic drugs are not merely ones which we, the sociomedical researchers, define as such. There is again evidence that consumers, well aware of the effects that some drugs have, use them for the psychotropic benefits. Two examples reported by participants were aspirins and certain cold pills taken for their sedative qualities. It is not unlikely that other drugs and substances are similarly used by consumers in ways far beyond the imagination of the researcher (but not, I occasionally suspect, from the imagination of marketing and advertising personnel).

4. We also need to know more about mechanisms for dealing and coping not only with stress but with other types of mood change. Parry was not being facetious when he suggested that considering the stress and strain in daily living, we might better focus not on why some people use psychotropic drugs but why so many do not. It is this non-drug response which deserves more emphasis. Several of us informally noted that patients respond to stress in many ways: they rest, withdraw from a troublesome activity, ignore it, or go out and have a good time, exercise or develop relaxation techniques. Since no one is claiming that the drugs currently in use are anything but ameliorative, perhaps a closer look at such behavior is warranted. After all, what would it mean if we learned that of all psychic distresses daily experienced, most were handled with varying degrees of success by such non-pharmaceutical methods? Several participants noted that such methods are not being systematically researched but if they were, it might again legitimize in the eyes of both the doctor and the patient the old advice about rest, vacations, play, as appropriate medical actions. Should any of these methods prove of use it would provide at least an alternative method of treatment — something many physicians claim they no longer have in this age of the wonder drug.

Turning now to the dynamics of psychotropic drug use, it is clear that we are also at a beginning. Taking a drug, like any other medical action, involves a decision. This is documented many times by the patients' 'negative' actions — their refusal to take their medicine, or their continual alteration of the time and dosage. This is not the result of laziness, stupidity, or ignorance, though it might be easier for us to think of it in this way. Moreover, a look at the studies of the lay public's medicine cabinet indicates they have a vast array of choices available (e.g. several different kinds of analgesics and sedatives) and thus we have to ask what factors affect the choice of drugs and (as

indicated from No. 4 above) alternative methods. Also we must realize, as we have for other medical actions such as utilization, that the decision to take a particular drug is not necessarily an individual, isolated act but may also take place in a social context of family or peer discussion.

Suggesting the type of research to be done is of course a giant step away from doing it. Numerous difficulties have already been cited by investigators at this conference. They have noted not only the unwillingness of the pharmaceutical industry to make much crucial data available but also a possible decrease in physician willingness to let their prescribing patterns be studied, as well as the bias in the sample of physicians who do cooperate. There was much reservation expressed about jumping from attitudes and reports of behavior to the actual behavior of patients and the problem of trying to cope with such problems through very expensive longitudinal studies. On the other hand, other conferees have spoken about their success in coping with just these issues. Bruun pointed out the growing legal and social pressures on industry to make many of their records and data on consumer behavior available. On this issue, Zola added that many market research firms may be approachable on this same topic and have indicated some willingness to share their data with 'responsible investigators.' Several intriguing new ways of using already existing data have been suggested by Pernanen. Sibley has presented a fascinating way of studying medical outcomes. Both he and Cartwright also indicated that through careful personal contact and persuasion an extraordinarily high degree of physician cooperation has been elicited. Cartwright has also shown how much can still be learned by intensive study of the doctor-patient relationship to illuminate 'the give and take of prescribing' despite the biases in a very selective sample. While not dealing with all the methodological difficulties, these papers at least outlined some stimulative beginnings.

With such specifics in mind we can perhaps turn to a more pervasive general theme. The study of the what, how, and why of psychotropic drug use would not be of concern were we not worried about its dangers. Though some caution was voiced that in many instances and for some persons the need of such drugs is *not* recognized, the general focus has been on 'over-generalized use.' One level of such concern was straightforward. This involved calling attention to the greater need for documentation of interactive and cumulative side effects, to the more insidious increase in adjunctive therapy, to the generally inadequate supervision and even acknowledgement of the long-term use of any drug. (The recent Balint, *et al.* studies were mentioned). A second level of concern dealt with a more pernicious effect of psychotropic drugs. Cooperstock, Muller and Wolfe noted the non-random distribution of prescribing patterns. In particular it was pointed out that the use for the elderly's depression and loneliness, the mental patient's aggressiveness, the woman's emptiness, the prisoner's rebelliousness, the ghetto child's disruptiveness, may represent a medical way of defusing a social problem. As Lennard and others pointed out this may be the greatest social danger of psychoactive drugs — namely their social masking effect. For we must realize that when we treat an individual with a drug for a social problem, along with whatever palliative effect it has on the individual, it has a similar palliative social effect as well. Simply put, if we can find any way to intervene with any problem on an individual level, then you may rest assured that little or no effort will be made on the social level. It is easier to view problems as matters of individual rather than social pathology. This is not really surprising. We have ample historical precedent for this comment. It was comforting to many and probably still is to think of the Nazi holocaust as the result of a leadership plagued with paranoid psychosis, psychopathic difficulties, sadistic personalities, and character disorders. I do not wish to deny

that Hitler, Goerring, Himmler, Goebbels were indeed crazy. I only wish to point out that great focussing on their pathology helps us beg the question of why 40 million people followed their insane lead and much of the rest of the world stood by watching.

Let me relate this issue to the context of drug use. To quote again one of the speakers, "One thing is certain, we cannot put the clock back. The future may have to be a compromise between chemical change and social change." I recognize this and further acknowledge that it is a dilemma for the physician on the firing line. There is, however, a story told by a physician about how he felt dealing with all the problems that come before him day after day.

You know, sometimes I feel like I am a man by the side of a swiftly flowing river. As I stand by the shore I hear a call. It's from a drowning man and so I jump in, I put my arm around his neck and drag him to shore and I apply artificial respiration. Then just as he's starting to breathe I hear another yell. So I jump in, put my arm around his neck, pull him to shore, apply artificial respiration. Then just as he's starting to breathe, there's another yell and so back in, to shore, artificial respiration. Again and again. You know, I'm so goddamn busy jumping in, pulling them to shore, applying artificial respiration that I have no time to see who the hell upstream is pushing them all in.

The fear I have is not in any principled objection to the idea of compromise. What I fear is that with the pressures on the physician to keep up with the continual and often overwhelming flow of problems, there will never be a possibility for a real compromise to take place. Instead there will be a continual opting for the change that can be accomplished — the chemical one.

I do not mean to draw a hopeless picture. Here too, many of the conferees have directed attention 'upstream' to stem the tide of psychoactive drug abuse. Continual reference has been made to the need for national and international legislation. There seems to be inadequate power and jurisdiction in current laws (Morrison), though the lack of enforcement seems more due to 'social pressures.' Whether it be on the international (Bruun) or the U.S. national scene (the Nader Reports), the picture of interlocking directorates and personnel exchanges between those who do the regulating and those to be regulated makes the claims of conspiracy against the Chicago Eight and the Spock group look ludicrous by comparison. Looking to the physician for help also seemed initially depressing. For not only is his pharmacological education woefully inadequate but his clinical orientation, class background and values may together place him in a position of feeling impotent about or unaware of the implications of what he is doing. Little solace was noted in studies of patient behavior. They showed the patients telling the doctor what he wanted to hear. A report that upwards of 40 per cent of patients do not follow exactly his physician's commands pointed up that the best measure of patient power was essentially a negative action. This was not by my way of thinking any great indication of activism.

So much for the bleak side. Looking on the optimistic side, we find indications of positive change on all fronts. On both the national and international scene there are growing watchdog and pressure groups. In fact, the very exposure of such interlocking personnel and self-serving legislation is an important forward step. While change in medical education proceeds slowly, there were some encouraging reports of physician peer control resulting in dramatic decreases in psychotropic drug prescribing (Wolfe). And on the horizon looms the growing consumer movement (Jones). Whether it be through

women's liberation or the growing number of mutual aid groups, it seems clear that patient's consciousness and, with it, passivity will never be the same.

I have tried to give a flavor of this conference. Perhaps most fairly, all I have been able to convey is what I have learned from this gathering. To the degree that I have learned, I wish to credit the mix of the participants: economists, sociologists, physicians, social psychologists, social workers. Somehow a real sharing of ideas has taken place, a sharing I believe difficult when we work alone and speak only to members of our own discipline. Several times you have been kind enough to compliment and use my remarks. To the degree they were insights, they were not bred in isolation but rather played off your concerns and articulations. I will project that this may well be true for many of the other insights produced by this group. I would like to maximize this by suggesting a further series of workshops, more focussed but with similar mixes of participants. Several come to mind. I would like to see one on medicine's role in the treatment of psychosocial stress. Is the doctor in the best position to deal with such problems? What of other occupations and professions? Can this part of medical care be delegated to others? What tools can be placed at the physician's disposal? What are the resources of the patient? Building on a report by Wolfe, another idea suggests itself: the peer evaluation and regulation of physicians. I would like to see more data on its implementation and maintenance. What will be the effects of new U.S. legislation like PSRO (Professional Standards Review Organizations)? Finally, I would like to see a workshop on the kind of information or power that could be put in the hands of the patient. There are certainly a lot of fears or myths about what will happen when patients have even more knowledge than they currently have or freer access to their medical records. What will be the implications of this for doctor-patient trust or even for the so-called placebo effect? But in addition to a greater focussing, each of these workshops including the present one must either grapple directly with social policy issues or develop a methodology of doing so. We must begin to deal not only with the idea of priorities but how we go about establishing them. We cannot shirk this responsibility by claiming that we do not have the skills. If not we, who? If not now, when? So let it begin here.

Contributors

Kettil Edmund Bruun is Research Director of the Finnish Foundation for Alcohol Studies. Born in Helsinki in 1924, Dr. Bruun received his M.A. in History, 1948, and his Ph.D. in Sociology, 1959, both from the University of Helsinki. From 1955 he has worked with the Finnish Foundation of Alcohol Studies. Amongst his numerous publications are: *Drinking Behaviour in Small Groups* (diss.) 1959; *Can Treatment of Alcoholism be Successful?* 1961 (with Touko Markkanen); *Drinking Habits Among Northern Youth*, 1963 (with Ragnar Hauge); *Inheritance of Drinking Behaviour*, 1966 (with Juha Partanen and Touko Markkanen), all in the series of the Finnish Foundation for Alcohol Studies; and *Alcohol – Its Use, Effects and Control*, 1972.

He was Chairman of the Board of the State Institute of Criminology, 1963-70; Chairman of the Finnish Social Science Research Council, 1971-73; WHO Expert Panel Member, and Member of the Board of A-clinic Foundation 1962-66. In 1971, Dr. Bruun received the Jellinek Award.

Ann Cartwright is the director of the Institute for Social Studies in Medical Care. Previously she was research director of the Medical Care Research Unit of the Institute of Community Studies and before that a lecturer in the Department of Health and Social Medicine at Edinburgh University. Publications include: *Human Relations and Hospital Care* (1964), *Patients and their Doctors* (1967), *Parents and Family Planning Services* (1970), *Medicine Takers, Prescribers and Hoarders* – with Karen Dunnell (1972) and *Life before Death* – with Lisbeth Hockey and John L. Anderson (1973) all published by Routledge and Kegan Paul.

Ruth Cooperstock is a Scientist in the Social Studies Department, Addiction Research Foundation, Toronto. She received her A.B. from Sarah Lawrence College, Bronxville, New York. She was previously a sociologist on the staff of the Psychiatric Research Unit, Department of Public Health, Province of Saskatchewan. Since coming to the Addiction Research Foundation in 1966 she has concentrated on problems of psychotropic drug use; her interests include the nature and extent of use, physician prescribing patterns, and sex differences in drug consumption. She has published articles related to these interests and currently serves in an advisory capacity to the Epidemiology section of the Non Medical Use of Drugs Directorate, Health Protection Branch, Department of National Health and Welfare.

Jean M. Jones received her B.A. from University of Western Ontario and her M.S.W. from McGill University. At present she is Associate Professor in the School of Social Work, McMaster University. Before joining McMaster, in 1968, when the School of Social Work was first established, she worked in medical social work, child welfare, community organization and social planning. Professor Jones' special interests in social planning and social policy include development of integrated delivery systems for health and welfare services and of self-help organizations. She has served as President of the Consumers' Association of Canada and is currently Chairman of C.A.C's Health Services Committee. She is a member of the Economic Council of Canada and of the National Health Grants Committee, Health and Welfare.

Henry L. Lennard is Professor of Medical Sociology (Psychiatry) at the University of California where he directs the Laboratory for the Study of Drugs and Social Behavior. Arnold Bernstein is Professor of Psychology at the City University of New York, and consultant to the Department of Psychiatry UC, SF.

Lennard and Bernstein have co-authored *The Anatomy of Psychotherapy and Patterns in Human Interaction*. Together with Leon J. Epstein, Professor of Psychiatry at the University of California, San Francisco, they have co-authored *Mystification and Drug Misuse*, Jossey-Bass Publishers, 1971, and Harper and Row, Perennial Library, 1972. Lennard is senior author of "Hazards Implicit in Prescribing Psychoactive Drugs," *Science* 1970; "The Methadone Illusion," *Science* 1972, and "A Solution of a New Problem," *The Smithsonian* 1973. In *Psychobiological Approaches to Human Behavior*, Stanford University Press, 1964, Lennard contributed the chapter on "A Proposed Program of Research in Sociopharmacology."

Alexander B. Morrison was born in Edmonton, Alberta. He obtained his B.Sc. and M.Sc. at the University of Alberta, his M.S. at Michigan, his Ph.D. at Cornell University, and is a Diplomate of the American Board of Nutrition.

In 1956 he moved to Mead Johnson and Company, Indiana, as a group leader in nutritional research. He joined the Food and Drug Directorate, Ottawa, in 1959 as a chemist, and became chief of the Nutrition Division in 1963. In 1966 he became chief of the Pharmacology Division, and was promoted to Director of Research Laboratories in 1968. Dr. Morrison was appointed Deputy Director-General of the Food and Drug Directorate in 1969, and Director-General (Research and Operations) in 1971. In 1971, he was appointed Assistant Deputy Minister, Food and Drugs and now serves as Assistant Deputy Minister (Health Protection Branch), Department of National Health and Welfare.

Dr. Morrison is the author of some 90 papers on various aspects of nutrition, biochemistry, toxicology and pharmacology. He is a Fellow of the Chemical Institute of Canada, a Fellow of the Royal Society of Medicine, a Borden Award Winner (1963) of the Nutrition Society of Canada, a member of numerous scientific societies, a Director of the Canadian Foundation for the Advancement of Therapeutics, and a trustee of the Food and Drug Law Institute. He was the President of the Nutrition Society of Canada for 1971-72. Dr. Morrison is visiting professor of pharmacology at the University of Toronto and during the summer of 1970, was a visiting professor of Toxicology at Albany Medical College of Union University, Albany, New York.

Charlotte Muller worked on financing of comprehensive fertility-related health services under a grant from the Ford and Rockefeller Foundations 1972-73, and on a study, published in 1973, of planning such services in Jacksonville, Florida. She has done research on health insurance for abortion, fertility care, drug addiction, and

mental health, and on capital investment in hospitals and nursing homes. Dr. Muller has studied prepayment for prescribed drugs, drug pricing and prescribing patterns. In March she testified before Senator Muskie's subcommittee on Barriers to Health Care for the Elderly. She teaches in the graduate program in urban planning at Hunter College. Dr. Muller has a B.A. from Vassar College, M.A. and Ph.D. from Columbia University.

Peter Parish graduated in Medicine from Sheffield University, England in 1956. After spending five post-graduate years training in internal medicine Dr. Parish entered general practice. In 1968, he was awarded a full-time research grant by the Department of Health and Social Security to study psychotropic drug prescribing in general practice and in 1969 was invited to take up his present position as Senior Research Fellow to the Medical Sociology Research Centre, University College of Swansea. He is working on a long-term program of research into the sociology of drug prescribing. He continues to practise part-time as a family doctor in a group practice in Swansea and is a member of the Royal College of General Practitioners (UK). Since 1968 he has been a member of the Action and Uses Sub-committee of the British Pharmaceutical Codex Revision Committee. He is also a member of the Swansea Advisory Committee on Drug Abuse in Young People and has published several reports on the medical use of psychotropic drugs.

Hugh J. Parry is Associate Director of the Social Research Group, The George Washington University, Washington, D.C. Since 1966, he has been Project Director of the Social Research Group's seven-year study of the acquisition and use of psychotropic drugs, working jointly with the Institute for Research in Social Behavior, Berkeley, California and with the support and close collaboration of the Psychopharmacology Research Branch, National Institute of Mental Health.

Dr. Parry has served as Director of Worldwide Survey Research, U.S. Information Agency; Project Director, Reactions Analysis Staff, Office of the U.S. High Commissioner for Germany; Chief, Troop Attitude Research, U.S. Forces, Europe; Director, Opinion Research Center, University of Denver; Officer-in-Charge, Evaluation Section, Office of the Secretary of the Navy. Universities at which he has taught include: Southern California, Denver, American and George Washington.

Principal publications include: *Public Opinion in Western Europe* (with L.P. Crespi), 1953; *Public Opinion and Propaganda* (contributor), 1954; *American Sexual Behavior* (contributor), 1955; "National Patterns of Psychotherapeutic Drug Use," *Archives of General Psychiatry* (with others), June, 1973; "Validity of Response in Survey Research" (with H.M. Crossley), *Public Opinion Quarterly*, Spring, 1950. Under the pen-name of "James Cross," he has published four novels and many short stories.

Kai PERNANEN is Research Scientist in the Social Studies Department, Addiction Research Foundation, Toronto. He received his M.A. in Philosophy and Sociology from the University of Helsinki, and was a researcher at the Finnish Foundation of Alcohol Studies between 1964 and 1968. He joined the research staff at the Addiction Research Foundation in 1969, and has mainly been working with alcohol use patterns in general population samples and methodological problems connected with this area of research. He is currently working on a trend and individual follow-up study of psychotropic drug prescriptions among subscribers to a prescription insurance plan.

John C. Sibley graduated in medicine from Queen's University, Kingston, Ontario in 1947 and following postgraduate training in Canada and the United Kingdom he established a consulting practice in internal medicine in Hamilton and Burlington, Ontario where he became Head of the Department of Medicine in the Joseph Brant Hospital.

In 1967 Dr. Sibley became associated with the newly developing Faculty of Medicine at McMaster University and at present is Assistant to the Vice President of the Division of Health Sciences and Professor of Medicine in the Faculty of Medicine. His interests have included the initial planning and development of a regional rehabilitation centre with its related regional programs; the development of new models for education of the health related professions; the development of post-professional educational programs of an interdisciplinary nature including the nurse practitioner program, and in addition, has been involved in undergraduate medical education.

Dr. Sibley's research interests have been primarily in the health care delivery area in Canada and in Africa. He has retained an active role as a community consultant in internal medicine in Burlington, Ontario and is a member of the Canadian Cardiovascular Society, the Royal College of Physicians (London) and a Fellow of the Royal College of Physicians of Canada, the American College of Cardiology and the American College of Physicians.

Samuel Wolfe is a Canadian, and received his MD from Toronto, his MPH and Dr. PH from Columbia. From 1951-58 he was a country doctor in Saskatchewan. From 1962-66 Dr. Wolfe was a Commissioner of Saskatchewan's pioneer medical care plan, and from 1962-68 was Director of the Saskatoon Community Clinic. From 1968-73 he was at Meharry Medical College, latterly as Director of the Office of Health Programs. Since mid-1973 he is Chairman, Community Medicine at Long Island Jewish-Hillside Medical Center and Professor of Community Medicine at SUNY — Stony Brook. He has authored numerous papers, has co-authored two books (both with Robin F. Badgley of Toronto), and is principal investigator of a long term study to measure the effects of alternative ways of providing health care.

Irving Kenneth Zola is currently Professor and Chairperson in the Department of Sociology, Brandeis University, Waltham, Massachusetts. He has conducted research on the patients' use of medical facilities, their perceptions of symptoms and expectations. Dr. Zola has been a consultant to WHO, the Social Rehabilitation Service of the U.S. Government, the Netherlands Institute of Preventive Medicine, several hospitals and medical schools, training programs for paramedics and emerging self-help patient groups. His recent writings include an analysis of patient decision-making, the role of medicine as an institution of social control, the development of mutual-aid groups, and a description of a recently created village for the severely physically handicapped.

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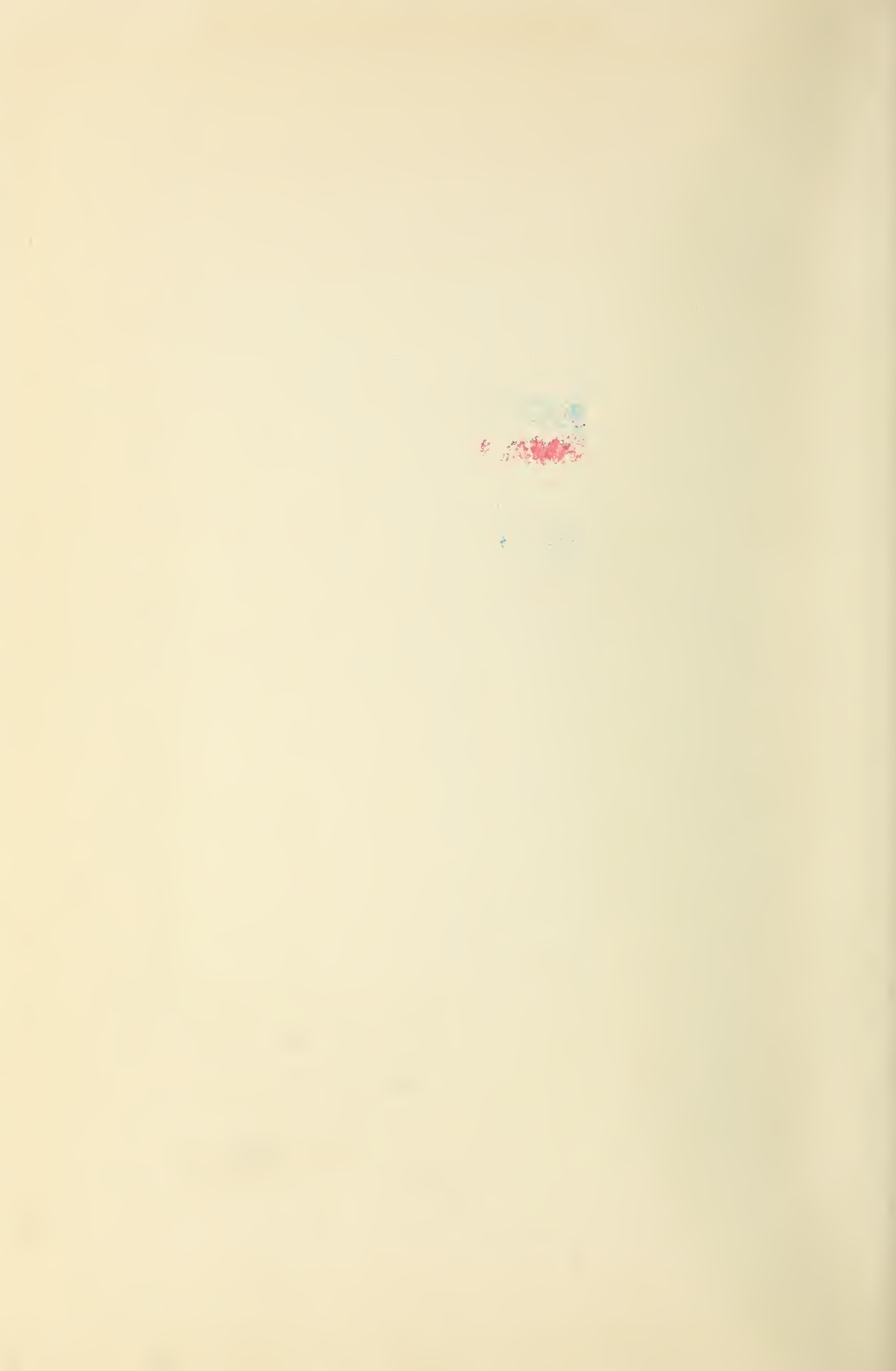
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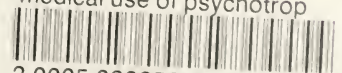


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